



# Analysis of the most appropriate regulatory management options (RMOA)

Substance Name: Poly- and perfluoroalkyl substances (PFAS)

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## EXECUTIVE SUMMARY

Poly- and perfluoroalkyl substances (PFAS) are a broad class of more than 9000 synthetic, fluorinated organic chemicals. Due to their chemical bond strength, these “forever chemicals” are slow to degrade and remain in the environment for many decades. Not only are these chemicals very persistent, but their wide breadth of use – identified across hundreds of global products – presents an even greater challenge around their potential management. Due to PFAS being detected in human blood samples, there has been growing concern about both widespread environmental contamination and human health risks from PFAS exposure.

The strength of PFAS is conferred by highly stable chains of varying lengths of carbon-fluorine (C-F) atoms. The beneficial properties of PFAS, which include tolerance to extreme temperatures and ability to repel oil and water, are a result of this unusual chemistry. This also leads to them being highly persistent in the environment and eliminated slowly from humans. With a scarcity of information on the toxicology of most PFAS substances, there is potential concern regarding the risk to human health.

The Health and Safety Executive (HSE), acting in its role as the Agency for UK REACH and supported by the Environment Agency, has examined the nature of the risks posed by PFAS and the most appropriate options for management of these risks. This assessment, termed a Regulatory Management Options Analysis (RMOA), is a non-binding technical document.

The RMOA aims to collect, combine and analyse information on the intrinsic hazards, uses and routes of exposure to PFAS, as well as consider relevant domestic legislation and international approaches to the management of PFAS. This information enables a clearer view of the risks of PFAS to human health and the environment, and derivation of potential regulatory options to minimise the identified risks. Whilst the options suggested focus primarily on the UK REACH framework, others are suggested where appropriate.

Human health or environmental risks arising from historic or discontinued uses of PFAS that are no longer permitted are not within the scope of this RMOA.

There is no single globally adopted definition of PFAS for human health or environmental regulation. For the purposes of this RMOA, PFAS are defined as:

**Fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups (–CF<sub>2</sub>–).**

This reduces the number of PFAS in scope to hundreds, maintaining focus on substances that are persistent degradation products of PFAS. In order to effectively investigate this range of substances, and to help prevent the regrettable substitution of individual PFAS on which action could be taken, a grouping approach has been implemented. The groups are based on structural similarity as an analogue for similarity in hazard profile. The groups were further refined to reflect the chemistry of the PFAS identified in UK and EU REACH registration databases to provide a representation of the PFAS on the GB market.

The UK REACH database of registered substances was used to gather information about PFAS manufactured or imported into GB. There are an estimated 2 600 – 36 700 tonnes of PFAS substances, across all groups, present on the GB market. However, this does not include substances manufactured or imported at less than one tonne per annum, substances still subject to transitional provisions following the UK's withdrawal from the EU, and substances incorporated into articles (finished products).

The greatest volume of PFAS potentially available on the GB market arise from a limited number of groups:

- polyfluoroalkyl substances – which find use in fire suppression systems and fire-fighting foams (FFF), foaming agents, refrigerant gases, the manufacture of electronic equipment, cleaning agents, consumer medical device
- perfluoroalkenes – which find use in isolation foams, and in the manufacture of polymers, petrochemicals and fine chemicals.
- Perfluoroalkanes and perfluorocycloalkanes – as used in cleaning agents, surface treatment agents, processing aids, refrigerant gases, heat transfer fluids and semiconductor manufacture.

A number of PFAS groups present at lower volumes are used in processes relating to the manufacture of textiles, upholstery, leather, apparel & carpets (TULAC). Where those processes occur in jurisdictions outside of GB, and are imported in the form of articles, these volumes may be unaccounted for. As such, these PFAS groups remain a concern due to a lack of available data.

Estimates of emission by industry sector indicate that the largest emissions arise from: F-gases, TULAC, and medical devices and medicinal products. This is followed by food contact materials; electronics (including batteries), construction, and FFF, in that order. All of these emissions are to air, water and land environmental compartments, except F-gases which only emit to the air.

Monitoring undertaken by the Environment Agency since 2014 suggests some PFAS are detectable in most groundwater, surface water bodies and biota in



**England.** Of these, short-chain PFAS are the most mobile, likely to be present in water compartments and have greater potential to bioaccumulate in air-breathing organisms. Long-chain PFAS are more likely to be associated with sediments and have a greater potential to bioaccumulate in aquatic and air-breathing organisms.

Occupational exposure to PFAS have been reported from industrial uses and indicated above, including manufacturing and processing aids. Exposure also arises from the professional use and application of chemicals such as FFF and fire extinguishing formulations/systems, and mist suppressants in chrome plating.

Dietary exposure is regarded as the primary non-occupational exposure pathway to humans. Drinking water can provide a dominant pathway for individuals using a point source-contaminated supply. Further exposure is possible via inhalation of indoor air/dust and dermal absorption through contact with materials and textiles impregnated with PFAS.

Legacy substances that are already regulated have been detected in the environment and are found in biomonitoring samples from humans and wildlife, emphasising extreme persistence. For example, although both perfluorooctane sulfonic acid (PFOS) and perfluorooctane carboxylic acid (PFOA) are now globally regulated as persistent organic pollutants (POPs), legacy contamination and pollution incidents associated with their uses continue to emerge.

The hazards of those legacy PFAS are generally well characterised. To understand the availability of information and hazards of less-well documented PFAS, a high-level assessment of substance groups was undertaken.

In some longer-chain PFAS, including those already undergoing regulatory processes, adverse developmental effects in laboratory animals was observed. Short-chain PFSA groups did not cause reproductive toxicity in the available animal studies. Although carcinogenicity has been raised as a concern for PFAS, no substance has been established as a human carcinogen. Genotoxicity has not been highlighted as a potential concern for PFAS.

Established environmental hazards, PBT and vPvB, and proposed PMT and vPvM have been considered at a grouping level, with persistence being the primary driver for action.

**In forming a conclusion, the Agency acknowledges that there is limited evidence on the human health hazard for many PFAS. Whilst toxicology data exists for a limited number of well-regulated PFAS, such as PFOA and PFOS.**

It is clear that the primary concern is to the environment, driven by extreme persistence.

The Agency has accounted for robust evidence that PFAS are extremely persistent due to their underlying C-F chemistry, are mostly mobile and as such can travel widely in the environment, and have been detected in many disperse human and environmental samples. They are extremely challenging to remove from the environment and are not readily excreted by animals.

Given that:

- PFAS will persist in the environment for long periods of time with a potential cause serious and irreversible damage, and
- that there remains uncertainty on the human health hazards of the majority of PFAS due to a lack of available data and limited understanding of long-term exposure
- There are uses of PFAS which are wide and dispersive with direct human exposure which (along with FFF and industrial processes) account for the main sources of PFAS into the environment

The Agency concludes that it would be appropriate, considering the Precautionary Principle, to initiate some or all of the following risk management measures with regard to certain uses of PFAS:

1. **Preparation of Annex XV dossiers to potentially support one or more restrictions of PFAS under UK REACH, including:**
  - a. the use and disposal of FFF where non-PFAS alternatives are available,
  - b. other wide dispersive uses such as the application of coatings or use of cleaning agents,
  - c. the manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water or soil, or directly transferred to humans. This includes textiles, upholstery, leather, apparel, rugs and carpets, paints, varnishes, waxes and polishes, cleaning products. Consideration may be given to other consumer articles if other gaps are identified in consultation with other legislative regimes such as food contact materials.
2. **UK REACH authorisation of PFAS used in processing aids in the manufacture and processing of fluorinated polymers**

3. **Further evaluation and investigation of substances that have been highlighted to be of concern**
  - a. Trifluoroacetic acid, EEA-NH<sub>4</sub> and perfluoroalkanes and perfluorocycloalkanes
4. **Continued collaborative work across government and with external stakeholders to bring together work on PFAS strategically, including:**
  - a. A review of the F-gas regulations to determine whether additional PFAS registered under UK REACH should be brought within scope
  - b. Development of statutory standards for PFAS in drinking water in England and Wales

## 1 INTRODUCTION

Poly- and perfluoroalkyl substances (PFAS) are a broad class of synthetic fluorinated organic chemicals which, due to their extensive use, high persistence and links to a range of adverse health impacts, have been identified as an issue that will need to be addressed.

Hundreds of PFAS are used commercially across many sectors of industry and society. They have a number of beneficial properties, such as durability to high temperatures and both oil and water repellence that provide for high quality products or efficient processes. There is a risk that health and environmental impacts of PFAS across a range of exposure routes are not being adequately controlled, resulting in avoidable health and environmental consequences. However, safer and more sustainable alternatives are not readily available for many of these uses (refer to section 2.4).

The number and diverse range of uses of this group of chemicals makes this a very challenging issue to tackle. PFAS pollution and impacts are a global problem. Action has already been taken to ban or restrict specific PFAS around the world, including in Great Britain (GB) e.g., perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA – refer to section 5.1 and 5.2 of this RMOA for further details). The exact nature of the issues and risks depends on differing circumstances in individual countries, but in some countries significant pollution incidents have been documented over the last 20 years. There is a need for GB to further assess the risks that PFAS pose and take forward actions to address these.

As part of the UK REACH Work Programme for 2021-22 (HSE, 2021), Defra and the Scottish and Welsh governments asked the Health & Safety Executive (HSE, in its role as the Agency for UK REACH and referred to as the Agency hereafter) and the Environment Agency (EA) to investigate PFAS in GB and “to consider how best to manage any identified risks”. This UK REACH Regulatory Management Options Analysis (RMOA) for PFAS has been prepared in response to that request.

To gather information to support this RMOA, the Agency held a 60-day call for evidence from 1 December 2021 to 30 January 2022. It requested information on all aspects of PFAS manufacture, import, hazard profile, use and exposure; including environmental fate, waste and its disposal requirements, recycling opportunities, and any legislation and standards that apply (including product-specific legislation and standards). All information from the call for evidence that has been used in preparation of the RMOA has been presented in a way that maintains commercial confidentiality.

Under the Northern Ireland Protocol, European Union (EU) REACH continues to regulate substances for the Northern Ireland market. UK REACH regulates substances, mixtures and articles manufactured, imported, marketed or used within GB. Human health or environmental risks arising from historic or discontinued uses of PFAS that are no longer permitted are not within the scope of this RMOA in terms of recommendations for regulatory management, though information on some of these PFAS such as PFOS and PFOA is included to inform this RMOA.

## 1.1 Substance Identity

### 1.1.1 The definition of per- and polyfluoroalkyl substances (PFAS)

There is no single globally adopted definition of per- and polyfluoroalkyl substances (PFAS) for human health or environmental regulation. The latest OECD Perfluorocarbon (PFC) Group (OECD, 2021) definition, which has also been adopted by the EU within its REACH restriction proposals (ECHA, 2022a), defines PFAS as: fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group ( $-CF_3$ ) or a perfluorinated methylene group ( $-CF_2-$ ) is a PFAS.

This RMOA has adopted a narrower working definition of PFAS, removing the criterion that a single isolated methylene group ( $-CF_2-$ ) is sufficient for classification as a PFAS. Hence, for the purposes of this RMOA:

**PFAS are defined as fluorinated substances that contain at least one fully fluorinated methyl carbon atom (without any hydrogen, chlorine, bromine or iodine atom attached to it), or two or more contiguous perfluorinated methylene groups ( $-CF_2-$ ).**

The rationale for this working definition is that compounds with a single isolated  $-CF_2-$  group are generally understood not to degrade to any of the highly persistent substances that have given rise to the environmental and/or human health concerns about PFAS (Buck *et al.*, 2021). Substances containing a **single isolated  $-CF_2-$**  are likely to be subject to biodegradation leading to breaking of the carbon–fluorine bonds and elimination of the fluorine atoms. For example, the fluorotelomer alcohols which possess a  $-CF_2-$  group adjacent to a  $-CH_2-$  group, have been shown to be readily degraded, breaking both  $-CF_2-$  carbon–fluorine bonds (Buck *et al.*, 2021).

These highly persistent PFAS of concern are often referred to as the ‘arrowhead’ substances; the term is applied to a PFAS that represents the

most stable transformation product of a precursor PFAS in the environment. In some cases, the arrowhead may be both a manufactured substance with its own commercial applications and a stable transformation product from one or more precursors (an example is perfluorooctanoic acid, PFOA). Figure 3.1.1 in Section 3.1 shows the potential degradation pathway of certain PFAS groups to the arrowheads.

The working definition adopted is, therefore, a pragmatic approach to restricting the scope of the RMOA to persistent PFAS. The number of non-persistent PFAS that are out of scope has not been determined.

The chronology of the development of PFAS definitions is summarised in Annex I, which provides additional supporting information for our working definition.

The working definition means that hundreds of PFAS are within the scope of this RMOA. An overview of PFAS and their groupings is presented in Section 1.2 below and Annexes II to IV, which illustrates the scale and nature of the challenge around identifying and categorising them.

### 1.1.2 PFAS with isolated CF<sub>3</sub>- moieties

A large proportion of the PFAS within scope of the definition used in this RMOA, and relevant to GB (refer to Section 2), have a single CF<sub>3</sub>- group (approximately 51% of PFAS registered in both EU and UK REACH). This group is also a component of many commonly used bioactive substances in pesticides and human and veterinary pharmaceuticals. Examples include haloxyfop-methyl and Prozac® (fluoxetine), which both have a CF<sub>3</sub>- group attached to an aromatic ring. The use of this functional group is a common strategy for modifying the pharmacokinetic properties of a substance by influencing its metabolic potential (Johnson *et al.*, 2020; Zhou *et al.*, 2016).

Ogawa *et al.* (2020) investigated the substances within the 18<sup>th</sup> Edition of the Pesticide Manual (Turner, 2018) and found that 202 of 1,261 (16%) of agricultural pesticides contained a per- or polyfluorinated alkyl group. Inoue *et al.* (2020) also estimated that organofluorine compounds could contribute up to 20% of commercial pharmaceutical products. At least some of these are likely to meet the working definition used for this RMOA.

The hazardous properties of pesticides and pharmaceuticals are primarily a function of the biological pathways being targeted, rather than being specifically caused by the fluorinated part of the molecule. The very wide diversity of structures also prevents any logical grouping into a single coherent PFAS category.

The CF<sub>3</sub>- group is likely to resist degradation, so trifluoroacetic acid (TFA) is likely to be a persistent transformation product of this type of substance. In evaluating the hazards and risks of TFA it is appropriate to consider all potential precursors and accordingly PFAS with isolated CF<sub>3</sub>- groups, including some pharmaceuticals, veterinary medicines and plant protection products, will fall within the scope of this RMOA (see Sections 3 and 4).

## **1.2 PFAS grouping**

This RMOA addresses the PFAS that are potentially on the GB market (as substances, mixtures or in articles), by applying a grouping approach to improve manageability and help address the issue of regrettable substitution (whereby regulatory action on a single substance may result in its replacement with structurally similar substances that have similar properties/hazards). The structural diversity of PFAS poses a challenge to grouping and there are different potential options. Cousins et al. (2020a) reviewed potential grouping approaches of PFAS and identified that the most precautionary grouping approach is based on their very high persistence alone (the so-called “P-sufficient” approach). The least precautionary grouping approach was identified as advocating only grouping those PFAS that have the same toxicological effects, modes and mechanisms of action, and elimination kinetics.

Within the range of grouping approaches noted by Cousins et al. (2020a), it was considered that grouping compounds with similar physical-chemical properties and structures would provide a useful first step in identifying the hazards and risks of PFAS. Hence, in this RMOA, PFAS have been grouped by structural similarity, based on the assumption that structurally similar substances are likely to pose similar hazards. Structural grouping enables group-level hazard evaluation, in which information about hazards obtained for particular representative PFAS is used to infer the intrinsic potential hazards of all related substances within the same group.

There are a number of challenges and shortcomings associated with using a structural grouping approach for PFAS. For example, groups will usually have trends in one or more properties which influence chemical bioavailability, and it can be challenging to identify an appropriate group boundary in the absence of comprehensive data. Bioaccumulation potential may increase with increasing alkyl chain length – up to a point – and can influence the decision to split groups into different chain lengths (such as the short- and long-chain perfluoroalkyl carboxylic acids (PFCAs) – refer to Table 1.2.1). An additional complication is that members of some groups may transform to arrowheads that are members of other groups. This applies, for example, to a number of

PFAS that can transform to PFCAs and perfluoroalkyl sulphonic acids (PFASAs). PFAS arrowheads and their precursors may pose distinctly different hazards and risks. Figure 3.1.1 in Section 3.1 shows the potential degradation pathways of certain PFAS groups.

Tables 1.2.1 and 1.2.2 present the PFAS grouping approach used in this RMOA.

Several published grouping approaches based on structural similarities were considered, i.e. Buck et al. (2011), OECD (2021) and the OECD fact cards (OECD, 2022b). These sources are summarised with examples in Annex II and, supplemented by work from Glüge et al. (2020), form the basis of the PFAS groups presented in Tables 1.2.1 and 1.2.2. The Agency initially collated and consolidated all the individual groupings presented by the various published sources to remove duplication and to ensure only those relevant to our working definition of PFAS were included. The groups were further refined to reflect the chemistry of the PFAS identified in UK and EU REACH registration databases to provide a representation of the PFAS on the markets.

PFAS families may be divided into two primary categories; non-polymeric and polymeric.

### **Non-polymeric PFAS**

- perfluoroalkyl substances – substances with a fully fluorinated carbon chain i.e., where all hydrogens in the alkyl chain are replaced by fluorine atoms
- polyfluoroalkyl substances – aliphatic substances in which all hydrogens atoms attached to at least one of the carbon atoms have been replaced by fluorine atoms.
- Fluorotelomer based substances - polyfluoroalkyl substances which are named using an “n:x” prefix where “n” indicates the number of fully fluorinated carbon atoms ( $n > 2$ ) and “x” indicates the number of carbon atoms that are not fully fluorinated ( $x > 1$ ).



**Table 1.2.1 Non-polymeric PFAS groups based on structural similarity**

Group	(Sub)-group criteria <sup>1</sup>
<b>Non-polymeric PFAS: Perfluoroalkyl substances</b>	
Perfluoroalkyl phosphonic (PFPA) and phosphinic (PFPIA) acids	<i>OECD Group 1</i>
Perfluoroalkyl carboxylic acids (PFCA) and precursors	<p><b>Short-chain PFCAs</b></p> <p>Contain &lt; 7 perfluoro carbons</p> <p><i>Sub-set of OECD Group 2</i></p> <p>i.e., Perfluoroheptanoic acid (PFHpA) and shorter carbon chain lengths</p>
	<p><b>Long-chain PFCAs</b></p> <p>Contain ≥ 7 perfluoro carbons</p> <p><i>Sub-set of OECD Group 2</i></p> <p>i.e., Perfluorooctanoic acid (PFOA) and longer carbon chain lengths</p>
	<p>Perfluoroalkanoyl fluorides (PACFs) and derivatives</p> <p><i>OECD Group 5</i></p>
Perfluoroalkyl sulfonic acids (PFSA) and precursors	<p><b>Short-chain PFSAs</b></p> <p>Contain &lt; 6 perfluoro carbons</p> <p><i>Sub-set of OECD Group 3</i></p> <p>e.g. Perfluorobutane sulfonic acid (PFBS)</p>
	<p><b>Long-chain PFSAs</b></p> <p>Contain ≥ 6 perfluoro carbons</p> <p><i>Sub-set of OECD Group 3</i></p> <p>i.e., Perfluorohexane sulfonic acid (PFHxS) and longer carbon chain lengths (Brendel et al., 2018) – includes perfluorooctane sulfonic acid (PFOS)</p>

Group	(Sub)-group criteria <sup>1</sup>
	Precursors include side-chain fluorinated polymers and perfluoroalkanesulfonamides ( <b>PASAs</b> ) Perfluorooctane sulfonyl fluoride ( <b>POSF</b> ) based products Includes perfluoroalkane sulfonyl fluorides ( <b>PASFs</b> ) and derivatives <i>OECD Group 6</i>
Perfluoroalkylether carboxylic acids ( <b>PFECAs</b> ) and precursors	<i>Sub-set of OECD Group 4</i> e.g. 3H-Perfluoro-3-[(3-methoxypropoxy)propanoic acid] (ADONA)
Perfluoroalkylether sulfonic acids ( <b>PFESAs</b> ) and precursors	<i>Sub-set of OECD Group 4</i> e.g. Hexafluoropropylene oxide dimer acid, (HFPO-DA)
Perfluoroalkyl ethers ( <b>PFEs</b> ), epoxides & vinyl ethers	<i>OECD Group 9</i>
Perfluoroalkanes & perfluorocycloalkanes	-
Perfluoroalkenes	<i>OECD Group 10</i>
Perfluoroalkyl <i>tert</i> -amines	-
Side-chain fluorinated aromatics (aromatic compounds with perfluoroalkyl moieties on the side chain)	Contains $\geq 2$ perfluorocarbons in perfluoroalkyl side chain <i>OECD Group 12</i>
	Contains only a single CF <sub>3</sub> - side chain <i>OECD Group 12</i>
Perfluoroalkyl alcohols	-
Perfluoroalkyl aldehydes and ketones	-
Perfluoroalkyl halides (i.e. iodide, chloride and bromide)	-
Cyclic PFAS with N and O in the ring	-

Group	(Sub)-group criteria <sup>1</sup>
Other perfluoroalkyl substances	Structures that do not strictly fit within the other groups identified.
<b>Non-polymeric PFAS: Polyfluoroalkyl substances</b>	
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), - ethers (HFEs), -olefins (HFOs)	<i>OECD Group 11</i> Includes semi-fluorinated alkanes
Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H, and O	Includes n:1 and n:2 fluorotelomer alcohols, aldehydes, ketones and ethers but does not include HFCs, HFEs, HFOs and carboxylic acids  <i>OECD Groups 7 and 8</i> <i>e.g. 3,3,4,4,5,5,6,6,7,7,8,8,8-</i> <i>Tridecafluoro-1-octanol</i> <i>(6:2 FTOH – a fluorotelomer alcohol)</i>
Polyfluoroalkyl substances: carboxylic acids (PolyFCAs)	-
Polyfluoroalkyl substances: ether carboxylic acids (PolyFECAs)	<i>OECD Group 4</i>
Polyfluoroalkyl substances: sulfonic acids (PolyFSAs)	
Polyfluoroalkyl substances: ether sulfonic acids (PolyFESAs)	<i>OECD Group 4</i> <i>e.g. 9-Chlorohexadecafluoro-3-</i> <i>oxanonane-1-sulfonic acid</i> <i>(F-53B)</i>
Polyfluoroalkyl substances: Fluorotelomer-based substances with N	-
Polyfluoroalkyl substances: Fluorotelomer-based substances with P	-
Polyfluoroalkyl substances: Fluorotelomer-based substances with S	Does not include polyfluoroalkyl sulfonic acids or ether sulfonic acids

<b>Group</b>	<b>(Sub)-group criteria<sup>1</sup></b>
Polyfluoroalkyl substances: Fluorotelomer-based substances with S and N	Does not include polyfluoroalkyl sulfonic acids or ether sulfonic acids
Polyfluoroalkyl substances: Fluorotelomer-based substances with Si	-
Polyfluoroalkyl substances: halides (i.e. iodide, chloride and bromide)	-
Polyfluoroalkyl substances (containing only a CF <sub>3</sub> - group <sup>2</sup> )	Organic compounds meeting the PFAS definition due to the structure containing a-CF <sub>3</sub> group <sup>2</sup> only but are not included in a group elsewhere e.g. side-chain fluorinated aromatics.
Other polyfluoroalkyl substances	Structures that do not strictly fit within the other groups identified.

<sup>1</sup> Reference to OECD fact card grouping of PFAS in italics.

<sup>2</sup> This does not include the simplest perfluoroalkyl substances containing a CF<sub>3</sub>- group (such as trifluoromethanesulfonic acid or the simplest side-chain fluorinated aromatics such as trifluoromethylbenzene).

## **Polymeric PFAS**

Polymers have a somewhat special status in UK and EU REACH in that they are exempt from the registration requirements. Instead of registering polymers, the monomers and other reactants that comprise the polymer are registered in their place. However, polymer substances are not exempted from other parts of REACH. As such polymers – including polymeric PFAS – may be subject to restriction under REACH. The monomers that comprise the polymers may also be covered by the restriction provisions of REACH, if required.

It is noted that because monomers used to create polymers are *de facto* intermediates, these monomers would be exempted from any authorisation provisions of REACH.

Within this RMOA, risks from polymeric PFAS have been assessed in terms of the groups representing UK REACH registered PFAS monomers and processing aids. Potentially persistent polymer degradation products are considered within the relevant arrowhead groups. However, no attempt has

been made to assess the likely levels of emissions of non-polymeric PFAS during service life and disposal of polymers.

### Polymer nomenclature

The nomenclature and grouping of polymeric PFAS adopted in this RMOA is similar to the system adopted by industry. The Fluoropolymers Group (FPG) of Plastics Europe divides fluoropolymers into three groups:

- fluoroplastics, corresponding to fluoropolymers in the RMOA grouping;
- fluoroelastomers, which are closely related to fluoroplastics; and
- perfluoropolyethers.

Side-chain fluorinated polymers are in a separate group entirely. These possess polyfluorinated chains that are chemically bonded to non-fluorinated polymer backbones (Buck *et al.*, 2011).

**Table 1.2.2 Polymeric PFAS groups based on structural similarity**

Group	(Sub)-group criteria <sup>1</sup>	Example(s)
<b>Polymeric PFAS</b>		
Side-chain fluorinated polymers	Includes fluorinated acrylate and methacrylate polymers, fluorinated urethane polymers  Related to <i>OECD Groups 7 and 8</i>	-
Fluoropolymers (fluoroplastics)	<i>OECD Group 13</i>	Polytetrafluoroethylene (PTFE)
Fluoroelastomers	Fluorocarbons, fluorosilicones, and fluorinated polyphosphazines  <i>OECD Group 14</i>	Polyvinylidene fluoride (VDF)
Perfluoropolyethers (PFPE)	<i>OECD Group 15</i>	Hexafluoropropene, oxidized, oligomers, reduced and hydrolysed

<sup>1</sup> Reference to OECD fact card grouping of PFAS in italics.

Annex I contains further information on the identification and definitions of non-polymeric and polymeric PFAS.

### **1.3 Summary and conclusions (including key uncertainties and data gaps)**

PFAS are a broad class of synthetic fluorinated organic chemicals for which there is no single globally adopted definition for regulatory purposes. The working definition of PFAS used in this RMOA differs from that adopted in other jurisdictions as it excludes PFAS with a single isolated methylene (-CF<sub>2</sub>) group. The proposed definition presents a pragmatic approach to restricting the scope of the RMOA to persistent PFAS and their precursors.

As hundreds of PFAS are still within scope of this working definition, a grouping approach has been used to improve manageability and help address the issue of regrettable substitution. Structurally similar substances were grouped based on the assumption that they are likely to pose similar hazards.

The PFAS definition adopted will have implications for the scope of risk assessments and any potential regulatory management measures. For example, by omitting substances containing a -CF<sub>2</sub>- group only, many fluorinated chemicals in potential use are not considered PFAS in our assessment. Hence, there are fewer fluorinated chemicals represented and considered for risk assessment and potential risk management measures compared to using the OECD (2021) definition. However, as discussed in Section 1, substances containing only a -CF<sub>2</sub>- group are not considered to degrade to arrowheads that have given rise to the environmental and/or human health concerns about PFAS. A generic PFAS definition may not be particularly useful from a regulatory perspective, and it may be more appropriate to consider regulatory approaches on the basis of particular PFAS groups and/or uses. As such, this is the approach adopted by this RMOA.

## **2 INFORMATION ON TONNAGE, USES AND EMISSIONS**

### **2.1 Tonnage and registration status under UK and EU REACH**

UK REACH is a regulation that applies to chemical substances that are manufactured in or imported into GB. UK REACH applies to all individual chemical substances on their own, in mixtures or in articles. Manufacturers and importers of substances are required to understand the hazards of the substances they are supplying to the GB market. If those substances meet the criteria for classification under the GB Classification Labelling and Packaging (CLP) Regulation or are identified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), manufacturers and importers are required to recommend measures for safe use of those substances.

At the time of searching the UK REACH registration database (June 2022), 36 individual PFAS were registered under the transitional registration provisions following the UK's exit from the EU (known as 'grandfathering'), allowing GB-based companies with existing EU REACH registrations to carry them over into the new domestic UK REACH system.

GB-based companies who imported PFAS from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to the Agency. An initial search of data submitted in DUIN submissions indicated at least 40 additional different PFAS imported from the EU at the time of searching (July 2022).

An additional 182 PFAS were identified in the EU REACH database (ECHA, 2022b; Accessed July 2021).

This information is summarised in Table 2.1.1 below.

**Table 2.1.1 UK and EU REACH relevant PFAS**

PFAS	Number of individual substances		
	UK REACH DUINs <sup>1</sup>	UK REACH <sup>2</sup> and EU REACH	EU REACH only <sup>3</sup>
Perfluoroalkyl substances	23	20	94 (17)
Polyfluoroalkyl substances	17	16	88 (14)
<b>TOTAL</b>	<b>40</b>	<b>36</b>	<b>182 (31)</b>

<sup>1</sup> Number of substances identified in downstream user import notifications (DUINs) in UK REACH; majority also have a parallel EU REACH registration listing but not all. DUINs should only have been submitted for substances imported from EU-27 countries, and should therefore all have an EU REACH registration. This discrepancy indicates that some DUINs were submitted inaccurately or in error.

<sup>2</sup> Registered substances which are listed in UK REACH and also listed in parallel in EU REACH.

<sup>3</sup> Registered substances in EU REACH only. These totals include the number of EU REACH registered substances that are also reported as DUINs in UK REACH, noted in brackets.

DUINs could be submitted for substances imported from the EU-27 (European Commission, 2022c) into GB at any point within the two years prior to EU exit. They represent an approximate snapshot of substances on the GB market in the period before EU exit. As DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution to be compliant). Consequently, the DUIN data needs to be treated with caution. Many former DUs will not (currently) have full information on the identity of the substances they import from the EU. This is because most substances are placed on the market as mixtures and the full composition of those mixtures is not always given on a Safety Data Sheet (SDS) or a SDS may not be required. In addition, many PFAS could be imported by multiple importers in lower volumes (i.e. below 1 tonne/year/importer); in these cases, the substances did not need to be included in a DUIN submission as there would be no registration duty under UK REACH for each importer. The DUIN information confirms that PFAS are imported from the EU. Given the wide range of uses for PFAS and the similarity of the GB market to those of larger EU member states (e.g. Germany, France, etc), it can be inferred that any of the EU registered PFAS could be present on the GB market at some level.

Information on volumes of PFAS in commerce and how they are used has been obtained from the UK and EU REACH databases of registered substances. However, these registration databases cannot provide a complete picture of the respective markets as they do not include PFAS manufactured or imported by individual companies below one tonne per year.



It is the case (more than likely) that PFAS are present in small quantities in semi-finished or finished imported goods (articles), but there is no requirement to register these imports unless the articles are designed to intentionally release the PFAS during service life and the aggregate import exceeds one tonne per year. Importers/suppliers may in any case be unaware of their presence, due to commercial confidentiality. In addition, there is no registration requirement for polymers under UK or EU REACH.

Submissions received during the call for evidence on this RMOA (held in 2021) included a significant amount of information on PFAS uses, mainly those associated with polymers, F-gases<sup>1</sup>, and perfluorocarbons (PFCs - some of which are also F-gases).

Table 2.1.2 summarises the tonnage information provided from the UK REACH registration database and lists the PFAS groups in order of highest aggregated tonnage.

Further details of tonnages for individual REACH (UK and EU) registered substances can be found in Annexes III and IV.

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<sup>1</sup> F-gases are highly volatile hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), sulfur hexafluoride and other greenhouse gases that contain fluorine.

**Table 2.1.2 Tonnages of manufactured and imported PFAS described in the UK REACH registration database**

<b>PFAS Group</b>	<b>Approximate UK REACH registered tonnage (t/y)<sup>1</sup></b>
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	1,000 - 15,000
Perfluoroalkenes	1,000 - 15,000
Perfluoroalkanes & perfluorocycloalkanes	200 - 2,000
Side-chain fluorinated aromatics (aromatic compounds with perfluoroalkyl moieties on the side chain) - Contains > 2 perfluorocarbons in perfluoroalkyl side chain	200 - 2,000
Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H and O	100 - 1,000
Perfluoroalkyl halides (i.e. iodide, chloride and bromide)	100 - 1,000
Perfluoroalkylether carboxylic acids (PFECA) and precursors	10 - 100
Polyfluoroalkyl substances: Fluorotelomer-based substances with S	2 - 20
Perfluoroalkyl ethers (PFE), epoxides & vinyl ethers	2 - 20
Other polyfluoroalkyl substances	2 - 20
Polyfluoroalkyl substances: sulfonic acids	1 - 10
Polyfluoroalkyl substances: halides (i.e. iodide, chloride and bromide)	1 - 10

<sup>1</sup> tonnes/year

The tonnages presented above do not include DUINs (potentially imported from EU at >1 tonne/year), or EU-REACH-registered and third-country-manufactured PFAS (which may be present on the GB market at <1 tonne/year) as discussed above. As such, the tonnage data based on UK registered PFAS does not represent a complete picture.

In addition to the PFAS groups in table 2.1.2 above, PFAS representing the following groups are imported into GB above 1 tonne/year according to DUIN submissions:

- PFCAs and precursors
- PFSAAs and precursors
- PFESAs and precursors
- Perfluoroalkyl aldehydes and ketones

- Perfluoroalkyl tert-amines
- Cyclic PFAS with N and O in the ring
- Polyfluoroalkyl substances: Fluorotelomer-based substances with Si

PFCAs and PFSAAs were further subdivided into short-chain and long-chain sub-groups based on the number of fully fluorinated carbon atoms (Table 1.2.1) given their distinct hazard properties and fate in the environment. Historically, long-chain acids, such as PFOS and PFOA, were used across a number of industries, and gave rise to the early concerns regarding PFAS. As long-chain PFAS have become increasingly regulated under EU and UK REACH, they have been gradually replaced by shorter chain perfluoroalkyl acids (PFAAs) as well as other PFAS and/or non-fluorinated alternatives. There was insufficient information regarding tonnages and use of short-chain vs long-chain carboxylic and sulfonic acid PFAS to allow an estimation of their relative tonnages.

## 2.2 Overview of uses

The earliest manufacture and use of PFAS dates to the discovery of the PFAAs in the 1930s and their large-scale production during the 1940s. The carbon-fluorine bond (C–F) is very strong. Consequently, PFAS can resist chemical attack and withstand high temperatures. PFAS such as the PFAAs are typically oil and water repellent, having been developed for use as surfactants and stain repellents. These properties make them useful in a broad range of processes and products. PFAAs such as PFOS and PFOA were commonly used in chrome plating, fire-fighting foams (FFF) and the manufacture of fluoropolymers prior to risk management activities to control their use (Environment Agency, 2021).

Use information for the registered substances was obtained from the UK REACH and EU REACH databases. Additional information was obtained from Glüge *et al.* (2020), OECD (2022b) and/or the EPA CompTox® database (US EPA, 2022b). Some of the use descriptions in the ECHA database were not complete or fully standardised, with detailed information for UK registered substances (with a handful of exceptions) not yet being available. Most substances are included in more than one use category.

PFAS are used globally and have a wide range of industrial, professional and consumer uses. Glüge *et al.* (2020) identified over 200 uses in 64 use categories across over 20 industry sectors. These included uses in or as:

- chemical intermediates and processing aids for fluoropolymer production;
- surface coatings for textiles, food contact materials and packaging;
- cleaning agents, varnishes, polishes and waxes;
- paints;
- printing inks;
- lubricants;
- cosmetics;
- pharmaceutical active substances;
- plant protection products;
- medical devices and products;
- feed additives;
- the electronics and energy production sectors;
- construction materials, including as polymers;
- heat exchange systems;
- fire suppression systems and fire-fighting foams; and
- mist suppressants for metal plating.

Information submitted during the GB call for evidence suggests that fluoropolymers and fluoroelastomers are particularly important to the industrial, automotive, aerospace and defence sectors, where uses include membranes, diaphragms, gaskets, seals and pipe linings. Side chain (C6) fluorinated polymers are used in coatings for textiles, upholstery, leather, carpets and paper. F-gases are of particular importance to the refrigeration, air conditioning and heat pump (RACHP) sector, and for foam blowing in the production of polyurethane foams. F-gases are also used in anaesthesia (sevoflurane, isoflurane) and in a number of specialist medical applications. Short-chain PFAS may be used at low concentrations (<0.1%) in household paints as fluorosurfactants.

Details of the specific uses identified by UK REACH registrants of PFAS are provided in Table 2.2.1 below.

Table 2.2.1 Summary of declared uses of UK REACH registered PFAS

PFAS Group	Number of PFAS	Declared Industrial, Professional and Consumer Uses
<p>Polyfluoroalkyl substances:                      Hydrofluorocarbons (HFCs), -ethers (HFEs) and -olefins (HFOs)</p>	<p>8</p>	<p><u>Industrial uses:</u>                      Manufacture of fire extinguishers and fire suppression systems                      Refrigerant Gas (heat transfer fluids) - including recycling/reclamation/destruction of waste/F-gas, manufacture of air conditioning systems                      Foaming agent                      Laboratory chemicals</p> <p>Industrial use as a monomer (polymerisation)                      Intermediate in the manufacture of fine chemicals, rubber products and plastics products;</p> <p>Washing and cleaning products                      Manufacture of fabricated metal products, except machinery and equipment                      Manufacture of computer, electronic and optical products, electrical equipment</p> <p><u>Professional uses:</u>                      Fire extinguishers                      Laboratory use                      Refrigerant Gas (inc. Installation, servicing and maintenance of equipment etc.)                      Foaming agent in the building and construction industry                      Solvent/cleaning agent</p> <p><u>Consumer uses:</u>                      Aerosol &amp; MDI (metered dose inhaler) propellant</p>

Perfluoroalkenes	2	<p><u>Industrial uses:</u> Industrial Use in Isolation Foams</p> <p>Use as a monomer and an intermediate in the manufacture of plastics products, rubber products and fine chemicals Intermediate - manufacture of bulk, large scale chemicals (including petroleum products)</p> <p><u>Professional uses:</u> Intermediate - Manufacture of bulk, large scale chemicals (including petroleum products)</p> <p><u>Consumer uses:</u> Not documented</p>
Perfluoroalkanes and perfluorocycloalkanes	10	<p><u>Industrial uses:</u> Semiconductors Laboratory Chemicals Cleaning/etching agent Solvent in polymerization process Calibration of analysis equipment Coolant and detector fluid Intermediate Non-metal-surface treatment products Use of non-reactive processing aid (no inclusion into or onto article) in the manufacture of bulk, large scale chemicals (including petroleum products) Applications in the medical field</p> <p><u>Professional uses:</u> Refrigerant gas - Heat transfer fluids (including installation, servicing and maintenance of equipment etc.) Laboratory Chemicals</p> <p><u>Consumer uses:</u> Refrigerants Hydraulic fluids Heat transfer fluids</p>

<p>Side-chain fluorinated aromatics aromatic compounds with perfluoroalkyl moieties on the side chain) - Contains &gt; 2 perfluorocarbons in perfluoroalkyl side chain</p>	<p>2</p>	<p><u>Industrial uses:</u> Intermediate - manufacture of fine chemicals</p> <p><u>Professional uses:</u> Not documented</p> <p><u>Consumer uses:</u> Not documented</p>
<p>Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H, and O</p>	<p>3</p>	<p><u>Industrial uses:</u> Manufacture of contact lenses Manufacture of rubber products Manufacture of plastics products Health services</p> <p>Polymer preparations and compounds - Manufacture of plastics products Textile Finishing - Manufacture of textiles, leather, fur</p> <p><u>Professional uses:</u> Washing and cleaning products Cosmetics, personal care products/Hair and Cosmetic shops Health services Polymerisation/Intermediate - Manufacture of plastics and rubber products, coatings and paints, thinners and paint removers Polymer preparations and compounds, textile dyes, and impregnating products Textile Finishing - Manufacture of textiles, leather, fur</p> <p><u>Consumer uses:</u> Washing and cleaning products Cosmetics / personal care products</p>
<p>Perfluoroalkyl halides (i.e. iodide, chloride and bromide)</p>	<p>1</p>	<p><u>Industrial uses:</u> Intermediate - Manufacture of fine chemicals</p> <p><u>Professional uses:</u> Not documented</p> <p><u>Consumer uses:</u> Not documented</p>

Perfluoroalkyl ether carboxylic acids (PFECAs) and precursors	1	<u>Industrial uses:</u> Manufacture of plastics products  Use as a processing aid and as a surfactant during polymerisation  <u>Professional uses:</u> Not documented  <u>Consumer uses:</u> Not documented
Polyfluoroalkyl substances: Fluorotelomer-based substances with S	2	<u>Industrial uses:</u> Intermediate  <u>Professional uses:</u> Not documented  <u>Consumer uses:</u> Not documented
Perfluoroalkyl ethers (PFEs), epoxides & vinyl ethers	2	<u>Industrial uses:</u> Reactant in polymerization process or use as intermediate in the manufacture of plastics products  Use as laboratory reagent Scientific research and development  Wire coatings, cable insulation and tubing  <u>Professional uses:</u> Not documented  <u>Consumer uses:</u> Not documented
Other Polyfluoroalkyl substances	2	<u>Industrial uses:</u> Coatings and paints, thinners, paint removers Fire-fighting foams  <u>Professional uses:</u> Fire extinguishing agents  <u>Consumer uses:</u> Not documented



Polyfluoroalkyl substances: sulfonic acids	1	<u>Industrial uses:</u> Metal treatment - Manufacture of fabricated metal products, except machinery and equipment Manufacture of computer, electronic and optical products, electrical equipment  Fluoropolymer and fluoroelastomer processing aid - Manufacture of rubber products Manufacture of plastics products, including compounding and conversion  <u>Professional uses:</u> Not documented  <u>Consumer uses:</u> Not documented
Polyfluoroalkyl substances: halides (i.e. iodide, chloride and bromide)	1	<u>Industrial uses:</u> Manufacture of charged Stationary Refrigeration & Air Conditioning / Mobile Air Conditioning (RAC/MAC) systems and other refrigeration machines Use of blowing agents in manufacture of foam Use of functional fluid at industrial site  <u>Professional uses:</u> Not documented  <u>Consumer uses:</u> Not documented

Further details of uses for individual UK and EU REACH registered substances can be found in Annexes III and IV respectively.

Three PFAS groups in particular stand out with a wide variety of industrial, commercial and consumer applications:

1. Polyfluoroalkyl substances: Hydrofluorocarbons (HFCs), -ethers (HFEs) and -olefins (HFOs)
2. Perfluoroalkanes and perfluorocycloalkanes
3. Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H, and O

These groups are associated with some of the highest tonnages (>1,000 tonnes/year or 100-1,000 tonnes/year bands) in UK REACH. Given the high tonnage and wide range of uses, a high potential for emissions (see Section 2.3 below) and widespread distribution associated with these uses is expected for these PFAS groups.

Information on the PFAS groups registered under UK REACH at lower tonnages suggests these substances have a narrow/more specific type of application.

### **2.3 Emissions**

In general, GB level emissions data for PFAS are very limited. Under UK and EU REACH, the requirement to undertake detailed exposure assessments is triggered for higher tonnage bands only, i.e. as part of a chemical safety report (CSR) for non-intermediates whose registration tonnage exceeds 10 tonnes/year. In addition, exposure does not need to be considered in the CSR if the registrant does not identify any hazards for the substance. As such, estimates of likely releases in this section should be considered indicative of relative volumes between different PFAS groups rather than reliable estimates of quantities entering the environment.

Emission estimates for PFAS groups representing UK registered PFAS were made with reference to ECHA's environmental exposure assessment guidance: Chapter R.16 (ECHA, 2016) . Release estimation has been undertaken using the annual tonnage data from UK REACH and the default emission factors for the uses identified in publicly available documents as summarised in the section above.

Within environmental exposure assessments undertaken in UK and EU REACH, environmental release categories (ERCs) are a conservative descriptor used to define the release factors of a substance in a specific environmental exposure scenario. The ERCs specify default values of the number of emission days and the fractions of the substance released to water, air and soil. For example, ERC1 is the 'Manufacture of a substance' with a default release factor to air of 5%, whereas ERC8a represents 'Widespread use of non-reactive processing aid' with a default release factor to air of 100%. More information about use descriptors is available in the ECHA guidance document on information requirements and chemical safety assessment; chapter on use description (ECHA, 2015b).

The tonnage and use information has been used in combination with the ERCs for the substances in the PFAS groups to provide an indicative ranking of potential releases as summarised in Table 2.3.1 below. Where multiple use categories were identified, the ERCs were weighted based on the number of times a specific use category was identified for a given substance/PFAS group in the reviewed documents. This was considered to provide an approximation of the likely volumes associated with specific applications in the absence of actual tonnage data for specific sectors and/or uses. Based on the calculated values, the emissions were ranked from highest release (represented by rank 5) to the lowest (1).

**Table 2.3.1 – Summary of declared tonnages and ranked release estimates of UK REACH-registered PFAS per PFAS group as identified in the UK REACH registration database; 5 represents the highest release rank, 1 – the lowest**

PFAS Group	UK REACH tonnage band (t/y)	Environmental release category (ERC)	Emission route	Annual release rank
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	1,000 – 15,000	ERC7, ERC4, ERC5, ERC8a, ERC9a, ERC9b, ERC10a, ERC10b, ERC8d, ERC6a, ERC6c + unspecified uses	air	5
			water	5
			soil	4
Perfluoroalkenes	1,000 – 15,000	ERC6a, ERC6c, ERC0, ERC1, ERC5 + unspecified uses	air	5
			water	5
			soil	4
Perfluoroalkanes & perfluorocycloalkanes	200 – 2,000	ERC7, ERC4, ERC5, ERC6b, ERC6a, ERC9a, ERC9b, ERC8a + unspecified uses	air	4
			water	4
			soil	4
Side-chain fluorinated aromatics (aromatic compounds with perfluoroalkyl moieties on the side chain) - Contains > 2 perfluorocarbons in perfluoroalkyl side chain	200 – 2,000	ERC6a + unspecified uses	air	4
			water	4
			soil	4
Polyfluoroalkyl substances:	100 – 1,000		air	4
			water	4

Fluorotelomer-based substances with only C, H and O		ERC6c, ERC8a, ERC8d, ERC5, ERC8c,	soil	3
Perfluoroalkyl halides (i.e. iodide, chloride and bromide)	100 – 1,000	None specified (assumed ERC6a)	air	3
			water	3
			soil	2
Perfluoroalkylether carboxylic acids (PFECAs) and precursors	10 - 100	ERC4	air	3
			water	3
			soil	2
Polyfluoroalkyl substances: Fluorotelomer-based substances with S	2 - 20	ERC6a	air	2
			water	1
			soil	1
Perfluoroalkyl ethers (PFE), epoxides & vinyl ethers	2 - 20	ERC6c, ERC6a, ERC6b, ERC7	air	1
			water	1
			soil	1
Other polyfluoroalkyl substances	2 - 20	ERC4, ERC8a, ERC8d	air	2
			water	2
			soil	1
Polyfluoroalkyl substances: sulfonic acids	1 - 10	ERC4, ERC6a	air	2
			water	2
			soil	1
Polyfluoroalkyl substances: halides (i.e. iodide, chloride and bromide)	1 - 10	ERC4, ERC5, ERC7	air	2
			water	2
			soil	1

The PFAS emissions estimates presented above are based on default emission factors taken from emission scenario documents (available on request). It should be noted that the emission factors in ECHAs guidance are very conservative and assume the worst-case scenario without considering the specific operational conditions or risk management measures (ECHA, 2016). **Therefore, whilst these estimates are likely to be unrealistic, they are the best available for ranking purposes.**

It has not been possible to verify emissions estimates through environmental monitoring data. No specific modelling has been undertaken as part of this RMOA. The available monitoring data have been considered further in Section 3.

There is often no information about what proportion of the total tonnage of a substance is used for any specific use. Many PFAS are used in both low and

higher emitting applications; this, combined with uncertainties regarding tonnage data and worst-case release factors, means there are large uncertainties in the emission estimates derived in this RMOA.

### **Emissions by industry/PFAS use sector**

Sector-specific information was reviewed, but frequently did not contain details of specific substances or tonnages used or such information was confidential. Therefore, direct comparison with the emission table above (Table 2.3.1) was not possible, and emissions by sector have been considered separately. Where available, emissions from these sector reports are presented in Table 2.3.2 below. To adjust EU data to GB context, the GB uses, tonnages and emissions were assumed to represent 10% of the values reported for the EU27 plus European Economic Area (EEA) and were corroborated by UK REACH-specific information, where available. The original reports were collected as part of the EU call for evidence on a broad PFAS restriction ([All news - ECHA \(europa.eu\)](https://www.echa.europa.eu/all-news)) and are available on request. The 10% scaling factor is acknowledged to be highly uncertain, and it is recognised that it will vary according to the use sector. The emission estimates for polymer products and articles manufacturing, and for non-polymer PFAS manufacturing, are similar in magnitude to those provided in the informal risk assessment reports published separately (Environment Agency, 2023a, 2023b, 2023c, 2023e, 2023f, 2023g, 2023h, 2023i, 2023j)

**Table 2.3.2: Summary of GB PFAS emissions estimates by industry sector**

<b>Sector</b>	<b>Tonnage in use (t/y)</b>	<b>Estimated emissions (t/y)</b>	<b>Environmental compartment</b>
F-gases	52,000	4,050	air
Textiles, upholstery, leather, apparel & carpets (TULAC)	4,100-14,300	110-390 (non-polymers)	air, water & land
		380-1420 (polymers)	
Medical devices and medicinal products	5,200	560	air (>70%), water & land
Food Contact Materials	Not reported	180 – 560	air, water & land

Electronics (including semi-conductors) & energy (including batteries)	150 (non-polymers)	55 (non-polymers)	air, water & land
	2,070 (polymers)	115 (polymers)	
Construction	740 (polymers)	59 (polymers)	air, water & land
	1,090 (non-polymers)	80 (non-polymers)	
Fire-fighting foams <sup>4</sup>	2,000	48-56	water & land
PFAS Manufacturing (polymer and non-polymer) <sup>2</sup>	Not reported	<50	air & water
Lubricants	482	22	air, water & land
Cosmetics	Not reported	0.9-1.8	water & land
Waste <sup>3</sup>	Not reported	1-1.3	water & land
Metals & Cr plating	Not reported	>0.6	air, water & land
Petroleum & mining	350 – 751 (polymers)	0.031 - 0.067 (polymers)	air, water & land
	<1 (non-polymers)	0.04 - 0.2 (non-polymers)	
Ski treatment	Not reported	0.1	air, water & land
Cleaning agents, polishes, and waxes	Not reported	Not reported	Not reported

### **Additional Information**

The UK Pollutant Release and Transfer Register (PRTR) is a publicly searchable database of pollutant releases from UK industrial sites and other specified sources, dating back to 2007. No specific category exists for PFAS compounds. However, release data are available for HFCs, PFCs and “halogenated organic compounds” which could approximately represent F-gases directly related to specific PFAS groups. A total of 131 tonnes of F-

gases were released to the environment from industrial sites in 2019 according to the UK PRTR (DEFRA, 2021).

It should be noted that industrial emissions, including from manufacturing, may only represent a small proportion of total emissions of chemicals such as PFAS, depending on the nature of the processes involved and sector use. As such, the PRTR figure above may capture emissions from manufacturing, formulation and industrial use, but would not include professional or consumer uses.

The figure of 131 tonnes, which represents the annual release of F-gases from industrial installations, is much smaller than the estimated F-gas emissions shown in Table 2.3.2. Within the GB call for evidence, sector reports gave the figure of 4,050 tonnes in total in the GB for 2018, i.e. more than one order of magnitude difference. The PRTR value does not include emission estimates from wide ranging consumer or professional uses, such as leakage from refrigeration and air conditioning equipment, which has been estimated at 5% of the total refrigerant stock (UK call for evidence submission; Tomlein and Tomlein, 2019).

## 2.4 Alternatives to PFAS

In considering the possible replacement of PFAS by substitutes or alternatives as a response to any risk management action, it is necessary to take into account their technical suitability, cost (economic feasibility), environmental and human health effects, as well as their capability to meet relevant required performance standards. Given the wide variety of substances in the PFAS group, along with the multitude of different uses as described earlier, a comprehensive analysis of alternatives that considers all suitability considerations is beyond the scope of this RMOA. Instead, the analysis focuses on the identification of the main alternatives to PFAS in so far as they are able to perform the main technical functions required, along with the main hazards associated with these alternatives. Given that PFAS are costly to produce, they are typically used in situations where alternatives cannot provide the necessary performance or where a smaller amount can be used for the same effect. More detailed consideration of their suitability would need to be considered in light of any specific risk management proposal, especially given the range of possible response behaviours that may be taken by industry in consequence of any particular risk management action on PFAS.

Glüge *et al.* (2020) identified almost 300 functions of PFAS, of which the main technical properties giving rise to the functions at a general level are:

- combined oil and water repellence;

- surfactant action (only some types);
- low coefficient of friction;
- resistance to high temperatures;
- low chemical reactivity;
- low flammability;
- low dielectric constant.

Table 2.4.1 below identifies chemical alternatives to PFAS in substances, mixtures and articles fulfilling particular uses for the relevant sectors. The main sources for this information were the EU call for evidence sector reports, three reports produced by the OECD and the GB call for evidence.

The three OECD reports cover:

- the commercial availability and current uses of PFAS and PFAS alternatives in coatings, paints and varnishes (OECD, 2022a);
- the commercial availability and current uses of PFAS and PFAS alternatives in food packaging (paper and paperboard) (OECD, 2020);
- a follow-up report on the hazards of PFAS and alternatives in paper and paperboard food packaging (OECD, 2022c).

For coatings, paints and varnishes, fluoropolymers were found to be the main PFAS in use, with short-chain PFAS used at low concentrations (<0.1%) in household paints as fluorosurfactants. In general, fluoropolymers tend to cost more than potential alternatives, so have achieved limited market penetration except where their properties are particularly advantageous (for example, in surface coatings for solar panels).

The reports on food packaging found that while potential alternatives with both grease and water repellence exist, the majority of alternatives lack adequate hazard assessments.

The OECD has also collated a number of reports on PFAS alternatives produced by member states (OECD, 2022d).

The majority of industry responses to the GB call for evidence took the view that whilst alternative substances exist for some uses, the performance would be poorer and might require greater mass of the substitute. For fluoropolymers and fluoroelastomers, the industry view appears to be that for



many or most uses there are no alternatives with the requisite performance characteristics.

The OECD definition of PFAS excludes some organofluorine substances that could be potential replacements for PFAS of concern. For example, pentafluorobenzenesulfonic acid (CAS no. 313-50-8) and hexafluorobenzene (CAS no. 392-56-3) do not meet the OECD definition but may still be highly persistent due to the strength of the C-F bond. In identifying alternatives, other organo-fluorine compounds that could pose similar or related risks have been avoided.

**Table 2.4.1: Overview of substance alternatives for PFAS**

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
<b>Cleaning agents, polishes &amp; Waxes</b>	Cleaner and demisting (glass etc.)	Enhance wettability by lowering the surface tension of the cleaning product  Prevents misting of glass – hydrophobic	- Hydrocarbon or silicone-based surfactants	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.
	Carpet Care	Provide water and oil repellence, stain resistance and soil release - Low surface tension, oleophobic  Fire-or weather resistance; non-flammable & stable	- Silicon dioxide (silica)	Chronic inhalation exposure to respirable crystalline silica may lead to concern for silicosis, lung cancer, or chronic obstructive pulmonary disease (COPD)
	Waxes & Polishes	Improve levelling and wetting - Lower surface tension  Aid spreading  Improve resistance of the polish to water and oil	- Carnauba wax	May be irritating to the skin and eyes.
	Windscreen wiper fluids/treatment	Prevent icing of windscreens	- Sodium dioctyl sulfosuccinate	May be irritating to the skin and eyes. May be harmful if swallowed.

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
<b>Food contact material &amp; packaging</b>	Packaging	Hydrophobic and oleophobic Low surface tension Non-reactive/stable	<ul style="list-style-type: none"> <li>- Natural greaseproof paper (e.g. intensively refined wood pulp)</li> <li>- Clay coatings</li> <li>- Silicone oils, resins and elastomers<sup>6</sup></li> <li>- Physical barriers: extra layer of plastic or aluminium onto the material<sup>5</sup></li> <li>- Other water barriers; alkyl succinic anhydride (ASA), styrene acrylic emulsion (SAE), alkyl ketene dimer (AKD) and rosin<sup>5</sup></li> <li>- Natural and synthetic cellulose fibres (bleached and unbleached)<sup>6</sup></li> <li>- Recycled fibres from paper &amp; paperboard<sup>6</sup></li> <li>- Siloxanes<sup>6</sup></li> <li>- high density paper which prevents the passage of grease<sup>8</sup></li> </ul>	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.  Silicone oils (with added preserving agent) may cause narcotic effects and be toxic to aquatic life with long lasting effects

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
	Consumer cookware	Hydrophobic and oleophobic  Low surface tension  Non-reactive/stable at high temperatures	- Ceramic coatings  - Silicone coatings/cookware  - Carbon /iron/stainless steel/copper	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.
	Industrial applications  Including - (Ovenware, non-stick coating to conveyor belts, seals/gaskets, tubing & pipes; blades of knives & scissors; springs; filter membranes sensor covers & lubricants).	Hydrophobic and oleophobic  Low surface tension  Non-reactive/stable at high temperatures	- Stainless steel/ceramic/silicone coatings  - Synthetic rubbers	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.  May contain phthalates (some may be potential endocrine disrupters)
<b>Lubricants</b>	PTFE (micropowder)	Friction reduction - form a thick layer to reduce wear  Friction reduction - form a thick oil layer to reduce wear  Non-reactive, non-flammable, operate also at high temperatures, do not form sludge or varnish	- Graphite  - Silicon dioxide (silica)  - Layer building zinc phosphates	Graphite dust may cause graphitosis  Chronic inhalation exposure to respirable crystalline silica may lead to concern for silicosis, lung cancer, or chronic obstructive pulmonary disease (COPD)
	PTFE thickened silicone oil	Friction reduction - form a thick oil layer to reduce wear  Non-reactive, non-flammable, operate also at high temperatures, do not form sludge or varnish	- Polyurea	May be irritating to the skin and eyes.

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
	High bearing aromatic thermosetting polyester coating	Friction reduction - form a thick layer to reduce wear  Non-reactive, non-flammable, operate also at high temperatures, do not form sludge or varnish	- Graphene	Unknown
<b>Construction</b>	Thermal insulation	Heat insulation	- Polyisocyanurate	Dust may be a mechanical irritant to skin, eyes and the respiratory tract
	Architectural fabrics	Resistance to weathering and sunlight  Dirt repellence	- Natural fibres  - Fiberglass  - Kevlar®/Twaron	May be irritating to the respiratory tract.
	Fluoropolymer tubing	Waterproofing (hydrophobic and oleophobic properties)  Durable/weather resistance and stability  Low surface tension	- Polyvinyl Chloride (PVC)  - Silicone	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.
	Coatings & additives (including paints and varnishes)	Highly durable and weatherable - low surface tension, oleophobic and hydrophobic  Non-reactive/stable - antistick and anticorrosive coatings	- Hydrocarbon & silicone based surfactants  - Polyether modified siloxanes  - Siloxane surfactants  - HDPE based products <sup>7</sup>  - Nano aluminium oxide <sup>7</sup>  - Polyurethane (PU) <sup>7</sup>	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties.

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
			<ul style="list-style-type: none"> <li>- PVC<sup>7</sup></li> <li>- Polyolefin and epoxy powders<sup>7</sup></li> <li>- Polyamides (PAs)<sup>7</sup></li> <li>- Polyethylene terephthalate (PET)<sup>7</sup></li> </ul>	
	Superhydrophobic coatings	Low surface tension, hydrophobic	- Polymeric matrix added to hydrophobic nanoparticles	Unknown
	Wood primer and inks	Enhance ink flow and levelling, improve wetting, aid pigment dispersion - low surface tension	- Sulfosuccinates	Unknown
	Rust protection	Rust protection	- Propylated naphthalenes	Possible aspiration hazard. May be toxic to aquatic organisms with long lasting effects.
<b>Metal plating &amp; Manufacturing of metal products</b>	Metal plating (chrome plating specifically)	Mist suppressant  Reduce the surface tension of electrolyte solutions	<ul style="list-style-type: none"> <li>- Alkane sulfonates</li> <li>- Amines</li> <li>- Paraffin oils</li> <li>- Foam blankets and other barriers which can be used instead of PFAS as mist suppressants for surface treatment of metals<sup>8</sup></li> </ul>	May include potential for skin, eye and respiratory tract irritation or be corrosive.

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
<b>Ski treatment</b>	Ski wax	Friction reduction  Waterproofing (hydrophobic and oleophobic properties)	- Hydrocarbon and paraffin  - Siloxanes  - Nanoparticles	Nanoparticles – environmental impacts are not well understood
	Alterations to the ski itself	N/A	- Microstructure modification  - Heating the base	Unknown
<b>Textiles, upholstery, leather, apparel &amp; carpets</b>	Home textiles	Waterproofing (hydrophobic and oleophobic properties)  Stain resistance/ Dirt repellency  Low surface tension	<i>Carpets:</i>  - Non-ionic polymer  - Ester Compounds  <i>Upholstery:</i>  - Hydrotreated naphtha  - Non-ionic polymer	Some ester compounds may be flammable.
	Outdoor wear	Waterproofing (hydrophobic and oleophobic properties)  Stain resistance/ Dirt repellency  Low surface tension	- Non-ionic polymer  - Ester Compounds  - Stearamidomethyl pyridine chloride <sup>8</sup>	Some ester compounds may be flammable.
	General use (multiple)	Waterproofing (hydrophobic and oleophobic properties)  Stain resistance/ Dirt repellency  Low surface tension	- Paraffin  - Ester/Hydrocarbons  - Organic solvents  - Linear & branched hydrocarbons	Some may be flammable (or combustible).

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
	Leather	<p>Improve the efficiency of hydrating, pickling, degreasing and tanning</p> <p>Provide water &amp; oil repellence, stain resistance and soil release (hydrophobic and oleophobic properties)</p> <p>Improve the levelling of shoe brighteners</p> <p>- Low surface tension</p>	<p>- Hybrid silicone &amp; hydrocarbon</p> <p>- Solvent silicone</p>	Silicone - Possible D4, D5 and D6 impurities with PBT/vPvB properties
	Other (home fabric treatment sprays)	<p>Waterproofing (hydrophobic and oleophobic properties)</p> <p>Stain resistance/ Dirt repellency</p> <p>Low surface tension</p>	- Alkyl polysiloxane	Unknown
<b>Petroleum &amp; Mining</b>	Water & Gas tracers	Non-radioactive, chemically and thermally stable, do not occur naturally, have very low atmospheric background concentrations	<p>- Radioactive/noble gas tracers</p> <p>- Xenon</p>	Radioactivity
	Drilling & Production (antifoaming)	<p>Foaming Agent</p> <p>Insulation</p>	<p>- Polydimethylsiloxane</p> <p>- Ethyl siloxanes</p>	Unknown
	Fluoropolymers		- Steel/other metal alloys	Unknown
<b>F-Gas</b>	Refrigeration	<p>Heat transfer</p> <p>Working fluid</p> <p>Non flammable</p>	<p>- Carbon Dioxide (CO<sub>2</sub>)</p> <p>- Propane</p> <p>- Isobutene</p>	<p>CO<sub>2</sub> is a greenhouse gas</p> <p>Propane &amp; isobutene are flammable.</p>
	Mobile air conditioning	<p>Heat transfer</p> <p>Working fluids</p>	<p>- CO<sub>2</sub></p> <p>- Propane</p>	<p>CO<sub>2</sub> is a greenhouse gas</p> <p>Propane is flammable</p>



Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
	Stationary air conditioning & heat pumps	Heat transfer Working fluids Non flammable	- CO <sub>2</sub> - Propane - Ammonia	CO <sub>2</sub> is a greenhouse gas Propane is flammable Ammonia (anhydrous) - flammable, corrosive, toxic if inhaled and very toxic to aquatic life
	Foam blowing agents	Prevent foaming	- Cyclopentane - Isopentane	Flammable
<b>Cosmetics</b>	Skin conditioners Eye Liners Face Masks Sun creams Anti-ageing creams Lipstick makeup removers Makeup removers Primer/fixers Hair-conditioning formulations	Waterproofing (hydrophobic and oleophobic properties) UV resistance Make the skin absorb more oxygen Make the skin brighter Skin moisturizer - makes creams etc. penetrate the skin more easily Enhance wet combing and renders hair oleophobic	Unknown	Unknown

Sector <sup>1</sup>	Uses <sup>1</sup>	Properties/Technical functions <sup>2</sup>	Alternative examples <sup>1</sup>	Indication of potential hazards for these alternatives <sup>3</sup>
<b>Emergency Response</b>	Fire-fighting foams: - Fluoroprotein (FP) foams <sup>2</sup> - Film-forming fluoroprotein (FFFP) foam <sup>2</sup> - Alcohol-resistant film forming fluoroprotein (AR-FFFP) foam <sup>2</sup> - Aqueous film-forming foams (AFFF) <sup>2</sup> - Alcohol-resistant aqueous film forming foam (AR-AFFF) <sup>2</sup>	Lower the surface tension of water	- Hydrocarbons <sup>4</sup> - Detergents <sup>4</sup> - Siloxanes <sup>4</sup> - Proteins <sup>4</sup>	May be irritating to the skin, eyes and respiratory tract. May have potential to cause allergic skin reactions. May be toxic to aquatic life.

Notes: <sup>1</sup> Information obtained from the results from ECHA call for evidence 2021 unless stated otherwise.

<sup>2</sup> Information obtained from Glüge *et al.* (2020).

<sup>3</sup> Information obtained from various searches for substance hazards in 'Google' search engine. Provides an indication

<sup>4</sup> Information obtained from (Wood *et al.*, 2020).

<sup>5</sup> Information obtained OECD (2020).

<sup>6</sup> Information obtained from (OECD, 2022c).

<sup>7</sup> Information obtained from (OECD, 2022a).

<sup>8</sup> Information obtained from KEMI (2015).

Table 2.2.1 shows that there are a wide variety of uses for PFAS substances. In most cases, the unique properties of fluorine (e.g. its very high electron affinity and the high carbon-fluorine bond strength) contribute to the desired properties of the substance. This could mean that alternatives in some applications will be difficult to find. However, potential alternatives have been identified as shown above and, previously, alternatives have been found when regulatory action was taken for specific PFAS (e.g. PFOS and PFOA). This suggests that alternatives can be found and are available for some applications.

Evidence from case studies (Glüge *et al.*, 2022) looking at substitution possibilities in the context of a range of different PFAS uses supports this view, but suggests that the possibilities may vary across uses depending on their complexity. In more straightforward cases, where the technical function of PFAS directly derives from their water and oil repellence, technical alternatives are more easily found. This will be the case, for example, in consumer products such as bicycle lubricants, carpets and cleaning products. However, in industrial applications where the conditions and requirements are more demanding, finding alternatives may be much more challenging, even if the technical function of PFAS is well defined, e.g. mist suppression in chrome plating.

These challenges are likely to be even greater in cases where PFAS perform several different technical functions and/or are used in multiple process steps. Even then, consideration of cost and performance will still need to be performed, alongside the need to sufficiently characterise and compare the hazards of the alternatives.

This means that risk management activities will need to take into account that substitution of PFAS may need to take place across different pathways and timescales, with due regard to the amounts and dispersive nature of PFAS used and released across particular uses. Further consideration of the issue of alternatives for the choice of appropriate regulatory risk management option chosen is made in Section 6. Nevertheless, it is clear that a more detailed investigation of the suitability of alternatives will be necessary to be undertaken as appropriate for any particular regulatory risk management option(s) chosen.

## **2.5 Summary and conclusions (including key uncertainties and data gaps)**

PFAS form a very large group of diverse substances, used in a vast range of industrial and consumer applications. Glüge *et al.* (2020) identified over 200 uses of more than 1400 individual PFAS. Nevertheless, robust evidence on the variety of PFAS, their volumes, uses and emissions for GB is limited. This presents a challenge in considering the nature of possible appropriate regulatory risk management options. This is further complicated by the need to understand the possibilities for substitution with suitable alternatives in response to any particular risk management option. The wide range of functions and uses that PFAS provide can mean that the assessment

of alternatives is complex and will require data on their safety, technical (including performance-related) feasibility, as well as their costs. Although some useful general evidence on alternatives is available, particularly in the form of case studies, a more detailed assessment would need to be undertaken according to the specific type of risk management option proposed.

### PFAS tonnages and uses

Whilst it is known that PFAS are used globally in a large number of industry sectors and in many industrial, professional and consumer uses, the information available in GB is not able to provide a comprehensive picture of volumes, uses and PFAS used. This is in part because, under UK REACH, companies that want to import, manufacture or market PFAS in excess of 1 tonne per year in GB have a long lead-in time for submitting transitional registrations, currently up to October 2027 for low tonnage substances that have not been identified as hazardous. Data waivers apply for low tonnage (<10 tonnes/year) registrations. This means that for many PFAS uses, UK REACH registration may not provide sufficient data to fully assess risks.

GB importers or distributors who previously relied on an EU REACH registration were required to submit DUINs, which contain very little information on tonnage. Little information is currently available regarding PFAS imported, manufactured or marketed within GB at tonnages below one tonne per year as there is no registration requirement under UK REACH for these substances. Likewise, little or no information is currently available for PFAS entering GB through imports of articles as there is no requirement to register these substances unless the articles are designed to intentionally release the PFAS during service life.

As noted in Section 1, polymers are exempt from registration under UK REACH, and are used in large volumes across a range of industries and consumer uses. Emissions associated with polymers may include potential polymer degradation products during article service life and disposal as well as non-polymeric PFAS (monomers and processing aids used in the polymer manufacture) that could be released during article service life. These emissions could not be quantified in this RMOA.

As a result, there is insufficient data on tonnages and uses in GB, including tonnages associated with specific applications, to reliably assess emissions, exposure or risks to the environment and human health from most PFAS groups.

Emissions were estimated based on standard emission factors, exposure scenarios and best available tonnage data. No reliable emissions monitoring datasets exist to corroborate those estimates, but worst-case scenarios indicate the potential for hundreds of tonnes of emissions to air, water and land per year. **The PFAS groups most likely to lead to the largest emissions as a result of being used in the highest**

volumes in a wide variety of industrial, commercial and consumer applications, have been identified as:

- Polyfluoroalkyl substances: Hydrofluorocarbons (HFCs), -ethers (HFEs) and -olefins (HFOs)
- Perfluoroalkanes and perfluorocycloalkanes

The PFAS groups which could be assessed most reliably were F-gases and fluoropolymers; further research and direct engagement with industrial sectors will be required to develop a fuller understanding of other PFAS groups manufactured, used or imported into GB.

#### Uncertainties around alternatives to PFAS (and their potential human health and environmental hazards)

As discussed earlier, there are a wide variety of PFAS on the market, having a diverse set of functions and uses. This diversity means that the assessment of alternatives is challenging and has significant information needs across the entire range of uses. Nevertheless, it is clear that alternatives do exist, particularly in less complex consumer uses. However, PFAS uses in industrial applications can have increased complexity, since the specific combination of properties of PFAS required in such applications are not readily matched by non-PFAS substances, making substitution much more difficult. Furthermore, many existing possible alternatives present potential human health and/or environmental hazards which require further investigation. In addition, there are economic challenges to substitution, as well as performance issues such that switching to suitable alternatives can only come at significant cost. Research and development will often be required to provide safe, technically feasible and cost-effective alternatives.

Given the variety of uses of PFAS and range of volumes involved, emissions and exposure are expected to vary greatly, and to be controlled by a range of potential risk management measures, including existing regulations which apply to the sectors concerned. Moreover, the range of potential risk management measures will need to take into account the challenges of substitution and the need for this to take place across different pathways and timescales, in accordance with the releases and exposures across sectors and uses.

Whilst it is difficult to draw out specific conclusions for possible regulatory risk management options on the basis of the use, tonnage, emissions and alternatives information in this section, one use that appears to be a reasonable candidate for possible action is in fire-fighting foams. Although relatively low concentrations of PFAS are used in fire-fighting foams, these foams and the PFAS they contain may be released directly into the environment. PFAS-free fire-fighting foams have been developed and are in use in most of the main sectors, possible regulatory action in

the form of restriction would be appropriate, although some use areas (e.g. petrochemicals) require more testing of the alternatives.

In terms of other areas for possible action, the following sections will analyse the hazard profiles of some of the PFAS groups, and the routes through which people and the environment may be exposed to them, in order to further consider the implications for regulatory risk management.

### 3 EXPOSURE AND MONITORING

Human and environmental exposure to PFAS in GB can be reasoned to be prevalent and comparable to that seen on a global scale. This is due to a combination of widespread and dispersive uses and their environmental fate, which is driven by their physicochemical properties, for example resistance to transformation and mobility. PFAS have been manufactured or imported into GB for over 90 years (Environment Agency, 2021) and are present in almost every aspect of our daily lives. How these substances are used and disposed of dictates when and where they enter the environment and subsequently humans. This is a critical consideration relative to prioritisation in the context of potential exposure.

The following chapter aims to set out:

- Sources of PFAS to the environment and humans
- Exposure pathways, fate and cycling for example of PFAS associated with industrial processes, firefighting applications, and consumer use in the general population
- Historical and contemporary GB monitoring data for the environment and humans
- Gaps in knowledge, evidence, and uncertainties.

#### 3.1 Sources of PFAS to the environment

PFAS enter the environment through their own production, use in different applications and during disposal. An overview of their global uses is presented in Section 2.2. The uses associated with PFAS substances that are registered under UK REACH are presented in Table 2.2.1. The following applications have been identified for the purpose of this report to illustrate exposure to both the environment and humans from point sources to wide dispersive uses. These applications are industrial processes, firefighting applications and consumer product use in the general population (e.g., household products, textiles, food contact materials etc.), respectively. Secondary sources such as waste management facilities (including landfill), wastewater treatment and biosolid production have been omitted at this stage, but they will be discussed in the context of environmental cycling later in this section.

Many individual PFAS used in industrial processes, firefighting applications and consumer products are identical or closely related at a group level (see Section 2.2). They have been detected in both the environment and humans (Section 3.2). Example PFAS groups associated with the selected applications are provided in Tabl.1 The use data was sourced from Glüge *et al.* (2020) and does not represent all uses related to the PFAS groups noted in the table.

Conversely, there are other PFAS substances used for these applications that do not belong to these groups. There are no data for the current volumes of PFAS within the groups named in Table 3.1.1 entering the GB environment or that humans are exposed to. However, as these sources have been globally identified as major primary routes of entry in both Europe and the USA (ITRC, 2022b; Kärrman *et al.*, 2019) we can adopt the position that as manufacturers and consumers of PFAS, the UK will also be subject to these major sources. Furthermore, monitoring data (see Section 3.1.3) reports widespread detection of the above groups in the UK environment. It can be justified that there is all encompassing exposure to these substances by both environmental receptors and humans.

**Table 3.1.1 PFAS groups associated with industrial processes, firefighting applications and consumer product use that are known sources of PFAS into the environment**

PFAS Group <sup>a</sup>	Industrial processes	Firefighting applications	Consumer products use
Short-chain PFCAs	Processing aids	Fire Fighting Foams (FFF) Textiles	Household goods Cosmetics Textiles
Long-chain PFCAs	Processing aids	FFF Textiles	Household goods Cosmetics Textiles
Short-chain PFSAs	Processing aids Metal plating	FFF Textiles	Household goods Textiles
Long-chain PFSAs	Processing aids Metal plating	FFF Textiles	Household goods Textiles
Other PFSAs	Processing aids Semiconductor manufacturing	FFF	Household goods Cosmetics Textiles Food contact materials
PFECAs	Processing aids	-	-
PolyFECAs	Processing aids	-	-
PFPAs and PFPIAs	Processing aids	-	Textiles
Fluorotelomers <sup>b</sup> (alcohols, betaines, fluorotelomer carboxylic acids (FTCA) and fluorotelomer sulphuric acid (FTSA))	Processing aids	FFF	Textiles Cosmetics Food contact materials

<sup>a</sup> The grouping is inclusive of precursors, intermediates, and arrowhead substances (many of which are substances in their own right), accounting also for different salts where appropriate

<sup>b</sup> The fluorotelomers are precursors of PFCAs and PFSAs



### 3.1.1 Exposure pathways to the environment from selected PFAS applications

Primary environmental exposure to PFAS from industrial processes occurs via solid waste streams with disposal via landfill, sludge spreading to agricultural land, or incineration with the atmosphere as the receiving environment; via liquid waste streams with disposal via wastewater treatment plant effluent discharges; and direct discharge to surface and ground waters.

Primary environmental exposure to PFAS from firefighting applications occurs through intentional use during firefighting training or response. FFFs will run off into receiving environments (e.g., drainage systems and surface waters) or will be absorbed into soils and reach groundwaters. One secondary exposure scenario to FFFs can occur through their disposal at end of life.

Consumer products that contain PFAS can lead to primary environmental exposure via solid waste streams with disposal via landfill, sludge spreading to agricultural land or incineration with the atmosphere as the receiving environment; via liquid waste streams with disposal via wastewater treatment plant effluent discharges; and direct discharge to surface and ground waters.

Once PFAS enter the environment they are subject to cycling. This is due to their longevity and stability, which are key properties desired of them in use.

### 3.1.2 The PFAS cycle

The PFAS cycle is very intricate (and overlapping) and is driven by complex partitioning processes between environmental matrices, biota etc. There are two dominant driving factors that impact the fate and transport (partitioning) of PFAS. These are well described on the Interstate Technology Research Council website (ITRC, 2022a; accessed October 2022; 2022b), which should be referred to for a more in-depth description. In brief these factors are:

- their intrinsic/inherent chemical properties that influence the type and extent of PFAS partitioning and transformation in the environment including chain-lengths, ionic state at environmentally relevant pH levels (pH 4 – 9), functional groups, extent of fluorination (per- versus poly-fluorinated), protein binding, etc.;
- the characteristics of the environmental sites that PFAS are being released into as point source, diffuse pathways or as a result of environmental recirculation (e.g. wastewater treatment works or irrigation). These characteristics include soil/sediment types with varying permeability, surface charge, organic carbon content, exchange capacity, mineralogy, water content, oxidation-reduction conditions, precipitation/infiltration rates, groundwater velocities, surface water flow rates, prevailing atmospheric conditions, and the presence of co-contaminants.

It is a challenge to describe the environmental fate and exposure pathways of PFAS as a family in the environment and in humans, and therefore the perfluoroalkyl acid arrowheads (PFAAs; e.g., PFCAs, PFSAs, PFPAs) will be described first, as the oldest of the substance groups. This is where most data are available for both the environment and humans. For human health studies, PFOA, perfluorononanoic acid (PFNA), PFHxS, and PFOS are those most commonly used in benchmarking and monitoring exercises. These substances are proposed to contribute the most to human exposure to PFAS (EFSA CONTAM Panel, 2020; Panieri *et al.*, 2022). This is discussed in more detail in Section 3.2. They also each have mandatory classifications for human-health effects (Section 4).

Environmental monitoring of the PFAAs in environmental samples has expanded in the last few years from just PFOA and PFOS to the entire homologue series for the PFCAs and PFSAs. However, as a whole it should be noted that in the environment PFAS comprise poorly characterised complex mixtures that consist of precursors and transformation products.

In this section of the RMOA, the term precursor refers to only those PFAS that can degrade to the PFAA arrowheads (See Annex VII for a brief description of potential degradation routes to arrowhead PFAAs). To give a sense of scale, Glüge *et al.* (2020) identified 1629 nonpolymeric PFAS, of which 227 are PFAAs and 1048 are “PFAA-based substances”, most of which are known or predicted precursors to PFAAs (McDonough *et al.*, 2022); UK monitoring encompasses fewer than 80 of these.

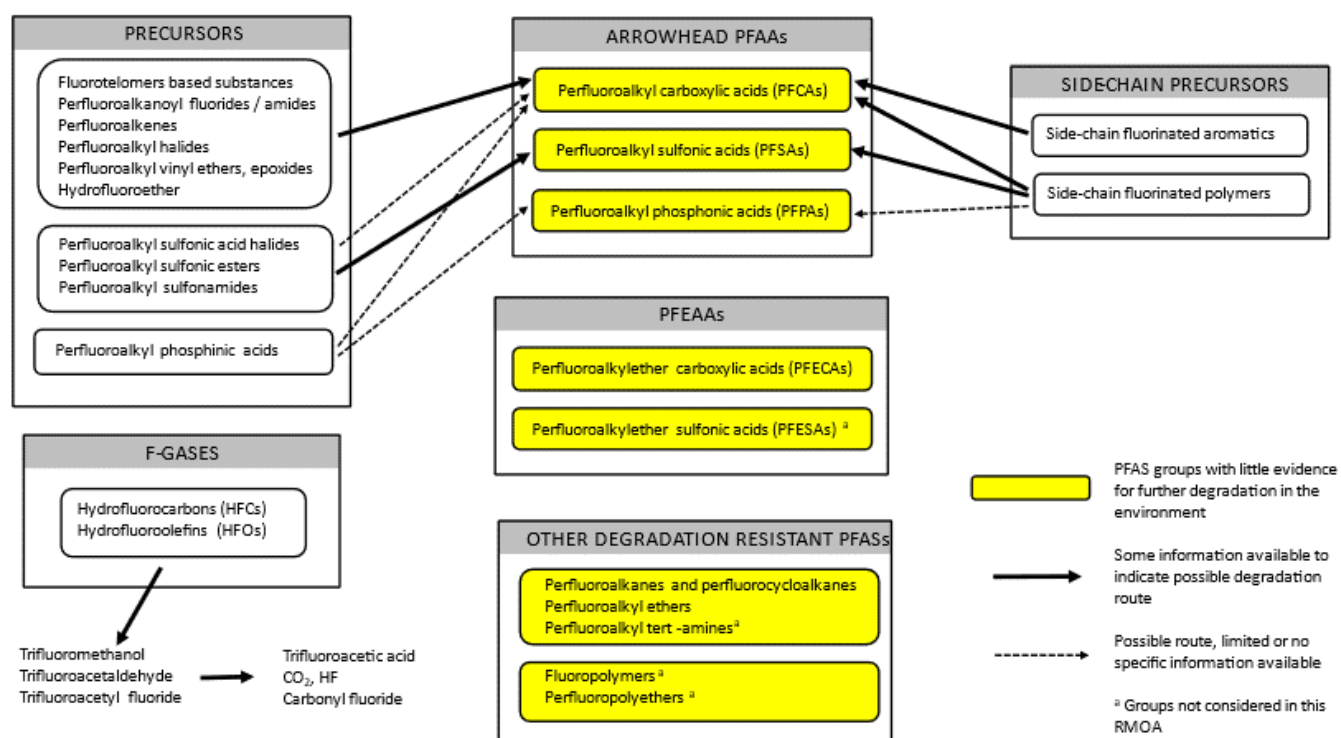
There are very few environmentally relevant degradation or transformation studies for precursor, intermediate or arrowhead substances. Subsequently, there is ambiguity around the extent to which precursor transformation occurs on any scale (e.g. regional to global), which environmental compartments represent the majority of transformation (e.g. soil or atmospheric), and what relevant conditions affect transformation processes, rates and pathways. Nevertheless, PFAAs are likely to present an increasing proportion of total PFAS in many vulnerable compartments such as drinking water sources and Groundwater owing to transformation and increased presence over time (ITRC, 2022b).

PFAAs do not appear to be metabolised or undergo chemical reaction in mammals (including humans), irrespective of their chain length (ATSDR, 2021). Studies to investigate the biotransformation pathways of fluorotelomer-based polyfluoroalkyl substances indicate that 8:2 fluorotelomer alcohol (FTOH) (which is the substance used in most of these investigations) is rapidly transformed to PFOA and, to a lesser extent, PFNA and lower chain-length PFCAs, albeit at low levels (Butt *et al.*, 2014).

PFAAs can be limited to a finite number of homologous compounds that vary by carbon chain length (e.g. 2 – 18 carbons) and terminal functional group (e.g. carboxylic, sulphonic, phosphonic or phosphinic acid). These can be used as

representative of many of the PFAS groups identified as relevant to applications discussed in this section, as the substance in their own right and also arrowheads of numerous precursors (e.g. FTOH or fluorotelomer sulfonate/sulphonic acid (FTS)). It should be noted that even within these structurally related homologue series, very different physicochemical properties can be observed even when they are closely related structurally, e.g. individual substances can range between volatile and non-volatile with only a few additional carbons in the back-bone of the molecule (Ankley *et al.*, 2021). The potential degradation pathways of PFAS groups are discussed briefly in Annex VII and presented in Figure 3.1.1 below, with the caveat that information on these pathways is often limited, not specific or the pathways have not been investigated.

**Figure 3.1.1** Potential degradation pathways of the PFAS in the groups containing UK REACH registered PFAS



In terms of persistence, bioaccumulation and mobility of PFCAs and PFSA, there are defined trends but not absolutes for the homologue series depending on the environment in which they reside. In general, many of these substances and their precursors are persistent in the environment (exceeding regulatory threshold criteria for all compartments whether the parent substance or the transformation product). Shorter chain-length substances (C<sub>≤7</sub> – PFCAs and C<sub>≤6</sub> – PFSA) undergo non-standard protein-driven bioaccumulation and are considered to preferentially undertake bioaccumulation in air-breathing organisms (e.g. mammals) rather than aquatic organisms (e.g. fish). Longer chain-length substances (C<sub>8+</sub> – PFCAs and C<sub>7+</sub>

– PFASs) undergo standard lipid-driven bioaccumulation and can accumulate in all biota (they have been detected in plants and animals).

Bioaccumulation is complex to define for the PFAAs especially where the carbon chain lengths are close to the definitions of short and long-chain lengths. De Silva *et al.* (2021) provided a thorough overview of the dominant processes associated with the different chain lengths, i.e. lipid- versus protein- driven. PFCAs and PFSAAs are mobile in the environment to varying degrees (Cousins *et al.*, 2020b), but ultimately do travel either in water, air or on particulate materials. This is due to a combination of their high water solubility, permanent ionisation under environmentally relevant conditions, surface active properties and concentration at which they are present in any media. For example, high concentrations can lead to increased retention in soils. This is due to micelle formation increasing their sorption to organic solids that then out-competes the repulsion from anionic inorganic soil components (which is the mechanism that dominates at low concentrations).

Once PFAAs and their precursors enter the environment they spread widely and recirculate. Figure 3.1.2 provides an overview of the pathways and environmental receptors for PFAS exposure via industrial emissions. For example, once aqueous industrial discharges containing PFAAs (and precursors) enter surface waters they can be subject to bioaccumulation in aquatic biota, entering the food chain (Chiesa *et al.*, 2022; Torres and De-la-Torre, 2022). These waters could also be used for irrigation of agricultural land or abstracted for drinking-water treatment. At this point the PFAAs can move to groundwaters through leaching (Johnson, 2022), or be subject to uptake in plants (McDonough *et al.*, 2021), entering the food chain via a terrestrial route (Wang *et al.*, 2020). PFAAs and precursors can move to the atmosphere through direct emission or volatilisation, or when bound to soil particles. They can therefore move over distances, returning to the terrestrial or marine environments through precipitation (Cousins *et al.*, 2022; Faust, 2022; Pfothenauer *et al.*, 2022), where they may move to sediments, bioaccumulate in biota or return to the atmosphere through sea spray aerosols (Sha *et al.*, 2022). **The application of biosolids and waste materials is considered a significant route of entry of PFAS to the environment and the food chain.** A review of accumulation of PFAS originating from soil amending materials to agricultural plants is provided in Ghisi *et al.* (2019).

**Figure 3.1.2 An overview of potential pathways and receptors which can be exposed to PFAS through industrial processes (Panieri *et al.*, 2022)**

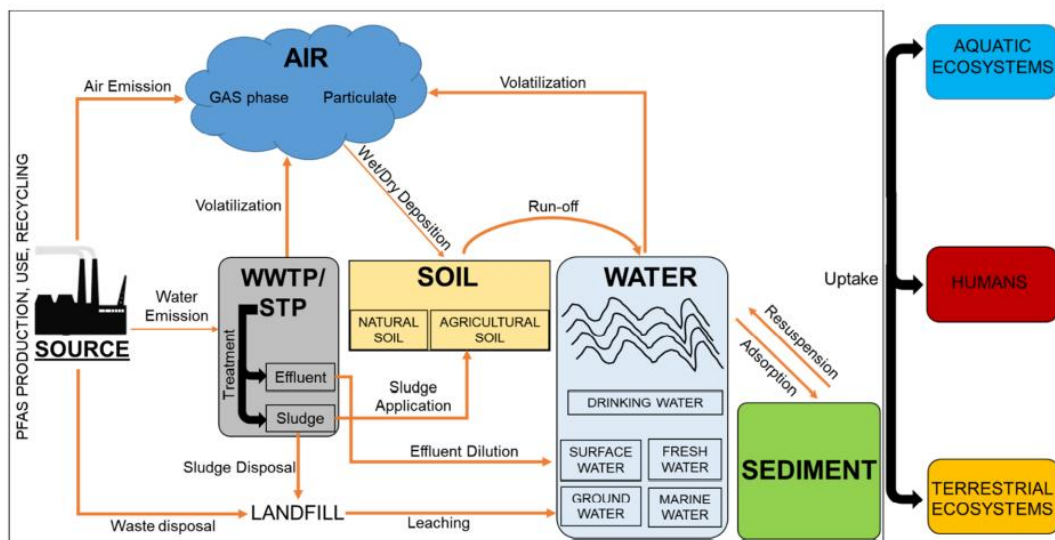


Image source: Panieri *et al.* (2022) © 2022 by the authors. Licensee: MDPI, Basel, Switzerland, Creative Commons 4.0, [CC-BY-4.0](https://creativecommons.org/licenses/by/4.0/)

These pathways contribute to both short- and long- term exposure of aquatic and terrestrial ecosystems and humans to PFAS. It is currently not well understood whether there is a true environmental ‘sink’ for these substances. However, if they are not continuously cycled and reach vulnerable environmental compartments such as groundwaters, they are likely to remain intact and increase in concentration over time.

### 3.1.3 Detection in the UK environment

This section sets out the current understanding of PFAS in the UK environment and presents an overview of national-scale environmental surveillance monitoring programmes and academic work. The Environment Agency (2021) summarised available PFAS monitoring data from the UK and this report has been used as the foundation to this section. Data from Scotland and Wales are also reported in Environment Agency (2021) but have been omitted from this document; this is because the English monitoring data are more extensive and can be extrapolated as providing a relevant picture for the whole of the UK.

Since publication of Environment Agency (2021), new data have been produced and further PFAS substances added to analytical suites. This has resulted in detection of legacy PFAS substances (precursors and arrowhead PFCAs and PFSAs), and ‘emerging’ PFAS substances (precursors and arrowheads) that are the replacements to those PFAS that have been regulated (see Section 5). The targeted monitoring suites are not all identical but do contain many commonalities, and therefore a substance might be present in a sample even if it is not detected. This will be examined later.

Individual substances from the following PFAS groups are currently monitored for in the UK:

- PFCAs and precursors – short and long-chain sub-groups, fluorotelomers etc.;
- PFSAAs and precursors – short and long-chain sub-groups, fluorotelomers etc.;
- Side-chain fluorinated polymers, PASA, POSF-based products, PASF and derivatives;
- PFECAs and precursors;
- PFESAs;
- Polyfluoroalkyl ether carboxylic acids;
- PFPAs and PFPiAs.

Apart from one substance in the PFECA and precursors group, these substance groups do not include any of the 36 UK REACH registered substances. They do, however, represent the potential transformation products/arrowheads of 10 of the UK REACH registered substances.

The Environment Agency holds monitoring data from groundwater, surface water (fresh, estuarine, and coastal waters), freshwater fish (roach (*Rutilus rutilus*), chub (*Squalius cephalus*), trout (*Salmo trutta*), marine fish (dab (*Limanda limanda*) and flounder (*Platichthys flesus*)), for a range of PFCAs and PFSAAs. Data from 2014 to 2019 reflect that monitoring activities during that time period focused on a small number of arrowhead substances (short- and long-chain PFCAs and PFSAAs), many of which are homologues of individual substances known or suspected to be hazardous (e.g. PFOA, PFNA, PFBS, PFHxS, PFOS) (Section 4). In addition, estuarine sediment sampling was undertaken through a collaboration between the Environment Agency and Centre for Environment, Fisheries and Aquaculture Science (CEFAS). Further UK environmental monitoring data (some of which is not currently published) have been provided by stakeholders of the H4 Emerging Risks Group (UK Gov, 2022). Contemporary data (spanning samples from 2018-2022) have been combined with those originally reported, thus generating a data set spanning 1977 to 2022. Concentration level data will not be presented at this time as many of these contemporary data are still undergoing quality assurance and control checks. Therefore, they will be treated as verified absolute detections of substances belonging to PFAS groups above the limit of detection (LOD) (e.g., targeted monitoring against certified reference standards). Concentrations have been omitted from the discussions unless considered relevant, but generally are at trace level spanning below the LOD to parts per billion ( $\mu\text{g/L}$  or  $\mu\text{g/kg}$ ) in a matrix, with few exceptions.

PFAS have been detected at elevated levels in soil or water associated with the use of fire-fighting foams e.g. Guernsey Airport (1999) and Buncefield Fuel Depot (2005).

### **Waters - surface and groundwater, estuaries and coastal waters**

Monitoring data from England (2014 – 2019) indicated PFAS are widely present in surface and groundwaters. At a PFAS group level, short-chain PFCAs and PFSA (e.g. PFBS, PFHxS, perfluorohexanoic acid (PFHxA), perfluoropentanoic acid (PFPeA)) were detected at the greatest percentage of groundwater, fresh and saline sites; and long-chain PFCAs (e.g. perfluoroundecanoic acid (PFUnDA) and perfluorododecanoic acid (PFDoDA)) were rarely detected in water samples. For inland surface waters, the water column based Annual Average (AA) EQS for PFOS is 0.65 ng/L. River quality assessment conducted by the Environment Agency between 2016 and 2018 indicated that this EQS was exceeded in over 90% of the surface waterbodies sampled.

Contemporary Groundwater monitoring data (2020-2022) has also identified FTSA, 6:2 FTS and 6:2 FTAB as the most widely reported in groundwater (Personal communication, Environment Agency, 2022)

UK water companies are monitoring source waters as part of routine sampling directed by the Drinking Water Inspectorate. Isolated samples have shown the presence of PFAS at low levels (Personal communication, DWI, 2022)

### **GB water monitoring – wastewater**

The Chemicals Investigation Programme (CIP) is a collaboration between water companies in England and Wales, the Environment Agency, and Natural Resources Wales (NRW), with the purpose of gaining a better understanding of the occurrence, behaviour, and management of trace contaminants in wastewater treatment processes and effluents. The second phase of the programme, CIP2, has effluent data from 609 wastewater treatment works (WWTWs) that were sampled between 2015 and 2020, together with associated upstream and downstream river samples. PFOS and PFOA were monitored in CIP2. The results from CIP2 indicated that whilst WWTWs add to the PFAS load, further investigation of sources of PFAS within catchments is required. Data for PFOA and PFOS show concentrations are highly variable between WWTWs.

Data from the third phase of CIP, CIP3, includes a wider analytical suite of targeted PFAS measured in waters (e.g. upstream and downstream of the works) and sewage sludge (e.g. PFBS, PFHxS, PFHxA, PFPeA, PFHpA, GenX etc.) These data are expected to be published in Spring 2023. In addition, investigations in CIP3 aimed to determine sources of PFOS and PFOA in sewer catchments and river catchments. A number of sources were identified, including abattoirs, tip leachate, petrol stations, car washes, nursing homes, iron phosphating effluent and commercial bakeries. A fourth phase of the investigation (CIP4) is anticipated.

## **Landfill Leachate**

UK landfill leachates have been analysed for the purpose of Persistent Organic Pollutant (POPs) reporting for Defra. This programme of work is extensive and includes boreholes up and down gradient of dilute and disperse landfills, modern treatments plants and waste sludges. Positive detections have been observed for targeted short- and long-chain PFCAs and PFSA, FTSA, FTCA and other precursor PFAS. These data will be published upon completion of the work.

## **Estuarine sediment**

CEFAS have analysed estuarine sediments from 15 estuaries around England that were sampled in 2020. The samples were analysed for 31 selected PFAS, from the following groups, PFCAs, PFSA, Perfluorooctane sulphonamides (FOSA), FTSA and several others. These data were reported in Barber (2021). In 85 of the 103 sediment samples collected, PFAS were detected above the limit of quantification. PFOS and PFOA were detected most frequently in 50% and 32% of sediment samples, respectively, with the highest concentrations most frequently associated with PFOS. Simpson *et al.* (2021) provides an advisory concentration limit for PFOS in sediment (60 µg/kg dry weight, normalised to 1% total organic carbon), which is considered protective of 99% of benthic species in the marine environment. This was exceeded in 5 of the 103 stations. At a group level the highest frequencies of detection were observed for short-chain PFCAs (perfluorobutanoic acid (PFBA), PFHxA, PFDA, PFHpA) and PFSA (PFHxS). The smaller short-chain PFSA, PFBS and perfluoropentane sulphonic acid (PFPeS) were infrequently detected in sediment (≤3 samples). This is not unexpected as the longer-chain substances are likely to be more sorptive to sediments, whereas lower chain-length substances are likely to remain solubilised in waters or partition to the atmosphere.

## **Atmospheric monitoring**

Atmospheric levels of PFAS are not routinely monitored for in the UK. However, a collaboration between the PERFORCE project, the Research Council of Norway and DEFRA provides UK data from 2005 and 2006. These are presented in Berger (2005) and Barber *et al.* (2007) for two English sites (semi-rural and urban). In brief, samples were analysed for selected precursors of PFCAs and PFSA (e.g. neutral fluorotelomers such as FTOHs), FOSAs and perfluorooctane sulfonamide ethanol (FOSE), and selected PFCAs and PFSA (short and long-chain). **Concentrations in urban air were higher than semi-rural.** All neutral precursor compounds were detected in the samples. The highest concentrations were noted for PFOA, 8:2 FTOH and 6:2 FTOH, which were ubiquitous in all samples. This was the first study to note that ionic PFCAs and PFSA, other than PFOA and PFOS, were present in air samples associated with particulate material.



## Soils

Measurements of PFAS in UK soils are not routinely performed. Work has commenced through the third phase of CIP to measure levels of PFAS in WWTW sludge destined for application to land and to characterise exposure via this route. Preliminary information indicates that analysis is targeted for short- and long-chain PFCAs and PFSAs, and a few arrowhead precursors. Full information from the third phase of CIP is expected to be published in late 2022.

Rigby *et al.* (2021) reported concentrations of short- and long-chain PFCAs and PFSAs associated with materials applied to UK agricultural land. Concentration of total summed PFAS decreased in the following sequence: biosolids > compost-like material > raw waste wood > dried paper sludge. Long-chain PFCAs dominated in raw waste wood and PFSAs dominated in biosolids and compost-like material.

## Biota Monitoring

Between 2014 and 2019, only PFOS and PFOA were measured in fish tissues (species noted below) by the Environment Agency. The presence of PFOS in both freshwater and marine fish from English waters is widespread, with concentrations ranging from < LOD to significantly above the Environmental Quality Standard (EQS) for biota of 9.1 µg/kg (UK Gov (2015)). The biota EQS was exceeded at 40% of the sites monitored by the Environment Agency between 2016 and 2018. The failure rate was 19% for saline waters monitored over the same period.

PFOA was not detected above the Limit of Quantification (LOQ) (1 µg/kg) in any fish sampled in the Environment Agency monitoring programme (Environment Agency, 2021).

O'Rourke *et al.* (2022) provided data from the liver tissues of 50 English otters (*Lutra lutra*) that died between 2007 and 2009. These data were generated as part of the Cardiff Otter Project (Otter Project, 2022; accessed October 2022). The highest concentrations of PFAS were noted for the long-chain PFCAs and PFSAs, corresponding to PFOS, PFOA, PFNA and PFDeA.

As part of the Predatory Bird Monitoring Scheme (PBMS; UK CEH, 2022; accessed October 2022), long-term trends in concentrations of targeted PFCAs and PFSAs in eggs from two UK colonies of the Northern Gannet (*Morus bassanus*) have been reported in Pereira *et al.* (2021). PFOS dominated the PFAS profile in the eggs of both colonies. Long-chain PFCA concentrations in eggs were noted to be increasing (with PFUnA and per-fluorotridecanoic acid (PFTTrDA) dominating the profiles). The authors noted that these compounds were not intentionally produced, and their presence could be attributed to their occurrence as impurities in PFOA and PFNA.

CEFAS measured levels of targeted PFAS in harbour porpoise (*Phocoena phocoena*) tissues stranded or by-caught in the UK during 2012-2014 (Barber *et al.*, 2016). PFOS was detected in all samples and comparison of data from 2012 to 2014

with an earlier CEFAS study (Law *et al.*, 2008) showed that the mean concentration of PFOS in UK harbour porpoises had decreased by approximately one third since 2001. (Barber *et al.*, 2016).

Androulakakis *et al.* (2022) monitored for 56 PFAS substances in the livers (n=5 pooled for all species) of UK apex predators and one fish species sampled between 2016 and 2017. This included UK samples of Roach (*Rutilus rutilus*), Buzzard (*Buteo buteo*), Eurasian otter and harbour porpoise. The 56 substances encompassed 14 sub-groups that included 13 PFCAs, 7 PFSA, 3 FOSAs, 4 PFAPAs, 3 (perfluoro phosphinic acids) PFPiAs, 5 FTOHs, 2 PAPs, 2 diPAPs, 6 FTAs, 3 FTUAs, 2 FOSEs, 3 FTSs, 2 PFECAs and 1 Cl-PFESA (F-53B; PFESA). Additional samples were analysed that originated from Germany and The Netherlands (there were variations in which PFAS were detected between the samples). The UK data have been summarised in the heat maps presented below. As a whole, the short-chain PFCAs and PFSA were detected more frequently in the apex predator liver than in fish liver. Long-chain PFCAs and PFSA were detected in all liver tissues and were dominated by PFOA (and other long-chain PFCAs) and PFOS (with the exception of UK buzzards). The UK buzzards were the only predator specimens in this study for which PFOS was not the predominant compound in the total PFAS burden. The most abundant was 8:8 PFPiA (41 %), followed by 6:8 PFPiA (24 %),  $\Sigma$ PFOS (21 %), 6:6 PFPiA (5 %) and 8:2 FTS (2 %). Alternative processing aids to PFOA, GenX (the ammonium salt of hexafluoropropylene oxide dimer acid (HFPO-DA) and ADONA (3H-perfluoro-3-[ (3-methoxy-propoxy)propanoic acid]), were not detected in any samples.

FTS, diPAP and PFPiA substances were prevalent in most liver samples. PFPiA substances are similar in terms of chemical structure to PFOS (Lee and Mabury, 2017) and can be expected to have similar physicochemical properties and bioaccumulation potential. The presence of the longer-chain PFCAs and PFSA are notable in apex predators, despite being phased-out. The most likely route of exposure for apex predators is through dietary intake, although in the absence of stable isotope data we cannot imply biomagnification or trophic magnification. The negligible detection of short-chain PFAS in all predators suggests they may have undergone biotransformation, been excreted, have low bioaccumulation potential or that predators are not being exposed to these substances.

Group-level monitoring data are provided in Figures 3.1.3 to 3.1.6 as heat maps of positive detections. These figures contain both unpublished data (analysis performed within 2020-2022) from monitoring campaigns that have extended their targeted substance suite, and data previously presented in this chapter (e.g. Pereira *et al.* (2021)). For each PFAS group the number of substances included in the monitoring suite is noted, alongside the number of positive and non-detects. A non-detect is below the LOD/LOQ of the method. The colour coding provides the percentage of substances in that group that were detected in the respective samples.

The figures have been split as follows, aquatic environments (groundwater, sediment and fish), air-breathing terrestrial and semi-aquatic mammals (fox and otter respectively), air breathing aquatic mammals (porpoises), and marine and terrestrial birds (gannet, buzzards and peregrines). With the exception of the gannet and peregrine egg samples, all animal samples are liver tissues. At a group level PFCAs and precursors are inclusive of FTOHs, FTAs, etc., PFSAAs are inclusive of FTS and FTSAAs etc. A discussion of transformation from precursor to arrowhead is presented in Annex VII and diagrammatically in Section 3.1.2.

**Figure 3.1.3 Group level detection of PFAS in groundwater, estuarine sediment, and fish livers from the UK**

Date range of dataset:	2021			2020-2021			2020-2021			2016-17		
Spatial range (Region/ England, Wales or Scotland):	England			England			England			UK		
Number of samples within dataset:	166			113			120			5		
Tissue/Medium	Waters			Sediment			livers			livers		
RMOA Grouping	Groundwater			Estuarine sediments			Dab ( <i>Limanda limanda</i> )			Roach		
Number of substances -	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	4	4	0	4	4	0	4	3	1	4	0	4
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	9	8	1	7	7	0	7	7	0	9	3	6
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	2	2	0	2	2	0	2	2	0	2	0	2
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	7	7	0	6	5	1	6	5	1	5	1	4
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Precursors include side-chain fluorinated polymers and perfluoroalkanesulfonamides (PASA) / POSF-based products / perfluoroalkane sulfonyl fluorides (PASF) and derivatives	7	7	0	5	4	1	5	5	0	5	1	4
Perfluoroalkylether carboxylic acids (PFECA) and precursors	4	4	0	2	0	2	2	0	2	2	0	2
Polyfluoroalkyl ether carboxylic acids	4	3	1	2	2	0	2	0	2			

100% of substances monitored detected
>50% of substances monitored for detected
>50% of substances monitored for not found
100% of substances monitored for not found
No substances monitored within sampling campaign

Monitoring campaigns - Groundwater (Environment Agency); Estuarine sediments (Defra and CEFAS); Dab (Clean Seas Environment Monitoring Programme (CSEMP) hosted by CEFAS) and Roach (Life APEX with reference to Androulakakis *et al.* (2022))

Figure 3.1.4 Group level detection of PFAS in otter and fox livers from the UK

Date range of dataset:	2015-2019	2016-17	2002-2018	2018-2021								
Spatial range (Region/ England, Wales or Scotland):	England	UK	UK	England								
Number of samples within dataset:	119	5	14	84								
Tissue/Medium	livers	livers	livers	livers								
RMOA Grouping	Eurasian Otter ( <i>Lutra lutra</i> )			Fox ( <i>Vulpus vulpus</i> )								
Number of substances -	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	4	4	0	4	1	3	4	1	3	4	1	3
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	7	7	0	9	5	4	9	7	2	7	7	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	2	2	0	2	2	0	2	1	1	2	2	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	6	6	0	5	3	2	4	3	1	6	6	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Precursors include side-chain fluorinated polymers and perfluoroalkanesulfonamides (PASA) / POSF-based products / perfluoroalkane sulfonyl fluorides (PASf) and derivatives	5	5	0	5	0	5	5	1	4	5	4	1
Perfluoroalkylether carboxylic acids (PFECA) and precursors	2	0	2	2	0	2	2	0	2	2	1	1
Polyfluoroalkyl ether carboxylic acids	5	4	1							5	4	1
Perfluoroalkyl phosphonic (PFPA) and phosphinic (PFPIA) acids	3	3	0							3	1	2

Eurasian otter data originating from the Cardiff Otter Project and Androulakis *et al.* (2022); Fox data originating from Natural England

100% of substances monitored detected
>50% of substances monitored for detected
>50% of substances monitored for not found
100% of substances monitored for not found
No substances monitored within sampling campaign

**Figure 3.1.5 Group level detection of PFAS in porpoise livers stranded or by-caught in UK waters**

Date range of dataset:	2018-2020			2016-17		
Spatial range (Region/ England, Wales or Scotland):	UK			UK		
Number of samples within dataset:	62			5		
Tissue/Medium	livers			livers		
RMOA Grouping	Porpoise ( <i>Phocoenidae</i> )			Harbour porpoise ( <i>Phocoena phocoena</i> )		
Number of substances -	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	4	3	1	4	0	4
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	7	7	0	9	4	5
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	2	1	1	2	0	2
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	6	6	0	5	3	2
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Precursors include side-chain fluorinated polymers and perfluoroalkanesulfonamides (PASA) / POSF-based products / perfluoroalkane sulfonyl fluorides (PASf) and derivatives	5	5	0	5	1	4
Perfluoroalkylether carboxylic acids (PFECA) and precursors	2	0	2	2	0	2
Polyfluoroalkyl ether carboxylic acids	2	1	1			

100% of substances monitored detected
>50% of substances monitored for detected
>50% of substances monitored for not found
100% of substances monitored for not found
No substances monitored within sampling campaign

Monitoring campaigns – Cetacean Stranding Investigation Programme (CSIP, [UK Cetacean Strandings Investigation Programme \(CSIP\) | Zoological Society of London \(ZSL\)](#) accessed October 2022. Monitoring performed by CEFAS

**Figure 3.1.6 Group level detection of PFAS in bird eggs and livers from the UK**

Date range of dataset:	1977-2014			2016-17			2002-2018			2002-2018		
Spatial range (Region/ England, Wales or Scotland):	UK			UK			UK			UK		
Number of samples within dataset:	110			5			14			20		
Tissue/Medium	eggs			livers			livers			eggs		
RMOA Grouping	Northern gannet ( <i>Morus bassanus</i> )			Buzzard ( <i>Buteo buteo</i> )			Buzzard ( <i>Buteo buteo</i> )			Peregrine ( <i>Falco peregrinus</i> )		
Number of substances -	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found	Monitored for	Positive detects	Not found
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	1	1	0	4	0	4	4	0	4	1	1	0
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	5	5	0	9	1	8	9	0	9	8	8	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain				2	0	2	2	0	2			
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	2	2	0	5	2	3	4	2	2	4	4	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Precursors include side-chain fluorinated polymers and perfluoroalkanesulfonamides (PASA) / POSF-based products / perfluoroalkane sulfonyl fluorides (PASf) and derivatives				5	0	5	5	0	5			
Perfluoroalkylether carboxylic acids (PFECA) and precursors				2	0	2	2	0	2			
Polyfluoroalkyl ether carboxylic acids												

100% of substances monitored detected
>50% of substances monitored for detected
>50% of substances monitored for not found
100% of substances monitored for not found
No substances monitored within sampling campaign

Northern gannet data originating from Pereira *et al.* (2021); Buzzard data originating from Androulakis *et al.* (2022); Failed peregrine egg data originating from Natural England

These figures provide evidence that multiple PFAS belonging to groups that are of legacy and emerging concern are present in the environment and biota in the UK. At a grouping level the detection of multiple precursors to the legacy contaminants, alongside groups that contain replacement PFAS (e.g. fluorotelomers as replacement to PFSA in aqueous film-forming firefighting foams, or PFECAs replacing PFOA as processing aids), demonstrate the complex mixture of PFAS that are present. In addition, the detection of the phosphonic and phosphinic acids and F-53B (a PFESA), which have no current registrations in UK or EU REACH for precursors or arrowhead substances, indicates that these substances are entering the environment through unidentified sources and uses.

### **Discussion of environmental monitoring data in the UK**

PFAS belonging to nine subgroups are observed in the historical and contemporary monitoring data of environmental compartments (waters, sediments, soils, air and biota) in GB (Figures 3.1.3 – 3.1.6). These subgroups represent the original substances of concern (short-chain and long-chain PFCAs and PFSA), their precursors (e.g. FTOH, sulfonamides, ether carboxylic acids, sulfonic acids and phosphonic acids) and replacements for those substances that have undergone regulatory action (e.g. PFOA, PFOS, PFHxS, etc.). PFAS of the targeted groups are detected widely in all compartments.

The distribution of PFAS groups between environmental compartments varies with their physicochemical properties. In brief:

- Short-chain ionic PFAS are considered more mobile, are more likely to be present in water compartments and have a greater potential to bioaccumulate (via protein driven mechanisms) in air breathing organisms. The negligible detection of short-chain PFAS in the apex predators included in the Androulakakis *et al.* (2022) study suggests that they may have undergone biotransformation, excretion, or that the organisms have not been exposed to these substances
- Long-chain ionic PFAS are more likely to be associated with sediments than waters and have been detected in the livers of aquatic and air-breathing organisms and avian eggs.
- Neutral PFAS groups that are more volatile than their ionic counterparts have been detected in UK air samples. These may transform through atmospheric photolysis to the arrowheads of concern and have a greater potential for long-range atmospheric transport. The significance of atmospheric transport and subsequent deposition to UK waterbodies and soils is an exposure pathway identified as an evidence gap.
- Temporal trends have been identified but are very difficult to explain with comparison against uses, primary and secondary exposure routes, environmental fate, etc. (e.g. Pereira *et al.* (2021)).



- The detection of the replacements and many of the precursors reflects changes in the analytical suites rather than sudden detectable concentrations. It is likely that many of these would be observed in historical samples if suitable methods had been available or archive tissues were available to retrospectively reanalyse.
- These data show that even with a shift away from the C<sub>8</sub> and higher chain-length chemistries due to regulatory management that they are still being detected alongside 'newer' lower chain-length and 'alternative' PFAS at measurable levels in the environment.
- The contemporary monitoring data have provided a picture of both the ionic acids, neutral precursors such as the fluorotelomers, and alternatives that were developed as replacements to those that have been regulated. Substances from these groups are likely to be present in the historical samples.

### 3.2 Human exposure and biomonitoring

Human exposure to PFAS arises from primary sources (consumer uses of PFAS-containing products, occupational exposures) and secondary sources (via environmental contamination of, for example, drinking water and food).

The most commonly studied PFAS are long-chain PFCAS and PFSAs, particularly PFOA and PFOS, followed by PFHxS and PFNA. The proliferation of novel PFAS has resulted in the rapid replacement of PFOS and PFOA with shorter chain-length PFAS and new chemicals that are difficult to detect with standard methods (Sunderland *et al.*, 2019).

Epidemiological studies often report exposure to several legacy PFAS (including branched and linear PFOS, PFOA, PFHxS, PFNA, perfluorodecanoic acid (PFDA)), but it is recognised that exposure analyses would be more comprehensive with the inclusion of additional PFAS that are increasingly relevant to current day production (Sunderland *et al.*, 2019).

The COT (2022) statement on the European Food Standards Agency (EFSA) CONTAM Panel opinion on the human-health risks from perfluoroalkyl substances in food (EFSA CONTAM Panel, 2020) provides human exposure data (in terms of dietary and non-dietary) on the following PFAS:

- Perfluoroalkyl carboxylic acids (PFCAs): for example, PFBA, PFOA, PFNA) and PFDA.
- Perfluoroalkane sulfonic acids (PFSAs): for example, PFHxS and PFOS.
- Other groups covering: perfluorooctane sulfinic acid (PFOSI), 8:2 fluorotelomer alcohol (8:2 FTOH), 8:2 fluorotelomer phosphate monoester (8:2 monoPAP), 8:2 fluorotelomer phosphate diester (8:2 diPAP), perfluorooctane sulphonamide

(FOSA), N-ethyl perfluorooctane sulphonamide (EtFOSA), N-ethyl perfluorooctane sulfonamidoethanol (EtFOSE) and ammonium bis[2-[N-ethyl (hepatodecafluorooctane) sulphonylamino]ethyl]phosphate (FC-807)

In this evaluation of PFAS exposure data, a mixture approach was used. A Tolerable Weekly Intake (TWI) of 4.4 ng/kg bw per week was established, based on the sum of four PFAS (PFOS, PFOA, PFHxS and PFNA). COT (2022) stated that the EFSA CONTAM Panel (2020) considered that the impact of the uncertainties on the risk assessment for the sum of PFOA, PFNA, PFHxS and PFOS was high.

The information on processes and exposure presented below are extracted from OECD Fact Cards (OECD, 2022b) of Major Groups of Per- and Polyfluoroalkyl Substances in 2022 (these uses will complement the industrial, professional and consumer uses identified in Table 2.2.1).

**Table 3.2.1 PFAS groups associated with occupational and non-occupational applications that are known sources of human exposure from a UK manufacturing and detection context.**

Group of PFAS	Manufactured in UK	Occupational processes, products and exposures:  e.g. production, manufacturing, industrial products	Non-occupational processes, products and exposures:  e.g. consumers, dietary, non-dietary, drinking water, indoor air & dust, soil and outdoor air etc
Perfluoroalkenes	Y	Production of copolymers  Additive for fire-fighting foams  Surfactant for oil production	Consumer uses:  Not documented  UK environment – natural waters, sediments etc.
Polyfluoroalkyl substances: HFCs, HFES and HFOs	Y  Note: HFCs are used in production processes – but are not produced in UK	HFCs are mostly used as substitutes for CFCs and HCFCs: in refrigeration and air-conditioning, as propellants in aerosols, and as foaming agents in closed cell foams.  Fire extinguishing systems, Propellants for	Air  Consumer uses: aerosol & MDI (metered dose inhaler) propellant

Group of PFAS	Manufactured in UK	Occupational processes, products and exposures:  e.g. production, manufacturing, industrial products	Non-occupational processes, products and exposures:  e.g. consumers, dietary, non-dietary, drinking water, indoor air & dust, soil and outdoor air etc
		<p>metered dose inhalers.</p> <p>Some HFEs are also used as inhalation anaesthetics.</p> <p>Production of fluorinated polymers and inert fluids</p>	
<p>PFECA and precursors</p> <p>Per- and polyfluoroether carboxylic acids</p>	Y	<p>A number of PFECAs (usually in the form of their ammonium salts) are used as fluoropolymer processing aids, to replace APFO and APFNAs as processing aid, specifically as emulsifier, in fluoropolymer production.</p>	<p>UK environment – natural waters, sediments etc.</p>
<p>Perfluoroalkyl ethers (PFE), epoxides and vinyl ethers</p>	Y	<p>Perfluoroalkylether chemicals mentioned here and mixtures thereof (perfluorinated fluids) are used in the electronics industry, as immersion coolants for supercomputers and testing applications.</p>	<p>UK environment – natural waters, sediments etc.</p>
<p>Perfluoroalkanes and perfluorocycloalkanes</p>	Y	<p>No info on the OECD fact cards</p>	<p>No info on the OECD fact cards</p>
<p>Side-chain fluorinated polymers, PASA, POSF-</p>		<p>PASFs are used as starting material in the synthesis of</p>	<p>Detected in the UK environment</p>

Group of PFAS	Manufactured in UK	Occupational processes, products and exposures:  e.g. production, manufacturing, industrial products	Non-occupational processes, products and exposures:  e.g. consumers, dietary, non-dietary, drinking water, indoor air & dust, soil and outdoor air etc
based products, PASF derivatives		sulfonamides and other derivatives including side-chain fluorinated polymers, which have been and are used as plant growth regulators, herbicides, in paper-protecting applications, and as surfactants and surface protection products in other applications. PASFs are precursors to PFSAs with the same chain length.	UK environment – natural waters, sediments etc.  Air  Consumer products
Polyfluoroalkyl ether carboxylic acids		A number of PFECAs (usually in the form of their ammonium salts) are used as fluoropolymer processing aids, to replace APFO and APFN.	UK environment – natural waters, sediments etc.
Perfluoroalkylether sulfonic acids (PFESA) and precursors		PFESAs like F-53B are used as PFOS substitutes, e.g. as mist suppressants in chrome plating.	UK environment – natural waters, sediments etc.
PFCAs and precursors – short-chain  TFA, PFPrA, PFBA: PFPeA, PFHxA, PFHpA		As a processing aid in the dispersion process for production of fluoropolymers  Surfactant	UK environment – natural waters, sediments etc.
PFCAs and precursors – long-chain		PFCAs have been used as polymerization	UK environment – natural waters,

Group of PFAS	Manufactured in UK	Occupational processes, products and exposures:  e.g. production, manufacturing, industrial products	Non-occupational processes, products and exposures:  e.g. consumers, dietary, non-dietary, drinking water, indoor air & dust, soil and outdoor air etc
PFOA, PFNA, PFDA PFUnDA, PFDoDA, PFTTrDA, Perfluorotetradecanoic acid (PFTeDA)		aids in the production of fluoropolymers, as surfactants, in insecticide formulations.  Historically, PFCAs were also ingredients of early generations of fire-fighting foams.	sediments etc. Consumer products
PFSA's and precursors – long-chain  PFHxS; Perfluoroheptane sulfonic acid (PFHpS); PFOS; PFNS; PFDS.		Longer-chain PFSA's are used as surfactants and in fire extinguishing formulations.	UK environment – natural waters, sediments etc.  Indoor air  Indoor dust  General population serum  PFOS and other long-chain PFSA's are known to be bioaccumulative and persistent in the environment, with PFHxS being the most bioaccumulative
PFSA's and precursors – short-chain  PFBS; PFPeS		Short-chain PFSA's are used as esterification catalysts, as electrolytes in fuel cells and batteries (in the form of their lithium salts), as antistatic agents, and as flame retardants (K-PFBS is mainly used as flame	UK environment – natural waters, sediments etc.  Indoor air  Indoor dust  General population serum  Short-chain PFSA's are less bioaccumulative, but are expected to

Group of PFAS	Manufactured in UK	Occupational processes, products and exposures:  e.g. production, manufacturing, industrial products	Non-occupational processes, products and exposures:  e.g. consumers, dietary, non-dietary, drinking water, indoor air & dust, soil and outdoor air etc
		retardant in polycarbonate).	be of similar persistence.  Consumer products
Perfluoroalkyl phosphonic and phosphinic acids		Surfactants, levelling and wetting agents in waxes and coatings, and defoaming agents in the textile industry, pharmaceutical industry, metal industry, and in pesticide formulations	UK environment – natural waters, sediments etc.  Indoor air  General population exposure levels  Consumer products

### 3.2.1 Human exposure pathways and biomonitoring

An overview of human exposure pathways has been briefly discussed in Section 3.1. Outside of occupational settings, the major sources of exposure to humans occur through dietary exposure (ingestion of contaminated drinking water and foodstuffs), Indoor exposure pathways, including inhalation of indoor and dust ingestion. There is also dermal uptake through contact with other media such as textiles containing PFASs (De Silva *et al.*, 2021; Panieri *et al.*, 2022; Sunderland *et al.*, 2019).

Researchers and regulators have sought to understand the contributions of different exposure pathways for PFAS to humans. The largest gaps remain for general populations with diverse pathways (De Silva *et al.*, 2021). The following section presents a summary of current understanding for human exposure, the majority of which has been drawn from other regulatory jurisdictions that have access to data and evidence that is currently not available in the UK.

#### **Occupational exposure**

The occupational exposure focus on PFAS has historically centred around the long-chain PFAAs, which include PFCAs with eight or more fully fluorinated carbons (for example, PFOA) and PFSAAs with six or more fully fluorinated carbons (for example,

PFHxS and PFOS), their salts, and precursor compounds capable of forming long-chain PFAAs.

Workers involved in making or processing PFAS and PFAS-containing materials are more likely to be exposed than the general population. The workers can be exposed to PFAS by inhaling them, getting them on their skin, and swallowing them, but inhalation is still regarded as the most likely route for exposure (ATSDR, 2022).

This is relevant to workplaces that produce or use PFAS (industrial sites) and downstream professional use (e.g. firefighters, chrome platers, etc.) (US EPA, 2022a). Detailed monitoring results for levels of PFAS measured in the blood of production and manufacturing workers at several perfluoroalkyl production and manufacturing facilities are available (ATSDR, 2021) and showed that the serum PFOA, PFOS, and PFHxS levels in workers were frequently 100–1,000 times higher than in the general population. Inhalation, dermal contact and ingestion are the major routes of occupational exposure (De Silva *et al.* (2021)). The major routes of occupational exposure are inhalation and dermal (De Silva *et al.*, 2021). The National Institute for Occupational Safety and Health (NIOSH) sponsored a study that suggests PFAS may be absorbed through the skin (Shane *et al.*, 2020), although the inhalation route is still regarded as the most likely route for occupational exposure.

The American Conference for Governmental Industrial Hygienists (ACGIH) has established Threshold Limit Values (TLVs) in the 'Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIS) publications (ACGIH, 2021) for three PFAS in air: perfluoroisobutylene (PFIB), perfluorobutyl ethylene (a fluorotelomer olefins) and ammonium perfluorooctanoate (APFO - a PFAA and a salt of PFOA). The TLVs (8 hr time-weighted averages and short term exposure limits - STELs) are: Threshold Limit Values (TLVs) in the 'Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIS) publications (ACGIH, 2021) for three PFAS in air: perfluoroisobutylene (PFIB), perfluorobutyl ethylene (a fluorotelomer olefins) and ammonium perfluorooctanoate (APFO - a PFAA and a salt of PFOA). The TLVs (8 hr time-weighted averages and short term exposure limits - STELs) are:

- Ammonium perfluorooctanoate [CAS 3835-26-1] 8 hour TWA TLV 0.01 mg/m<sup>3</sup>. No STEL.
- Perfluorobutyl ethylene [CAS 19430-93-4] 8 hour TWA TLV 1020 mg/m<sup>3</sup>.  
Perfluorobutyl ethylene [CAS 19430-93-4] 8 hour TWA TLV 1020 mg/m<sup>3</sup>. No STEL.
- Perfluoroisobutylene [CAS 382-21-8] No 8 hour TWA. TLV set STEL 0.08 mg/m<sup>3</sup> as a ceiling value (so not to be exceeded).

Along with the ATSDR (2021) report, which is focused on perfluoroalkyl compounds, other researchers have investigated occupational exposure to PFAS, although

research papers into exposure appear to be quite limited outside of firefighter exposure studies.

Although the use of ski wax aerosols and fumes by ski technicians is a niche exposure source within the UK, ski technicians have been researched as an exposed group within the international context. Freberg *et al.* (2014) measured exposures of professional ski waxers to ski-glide waxes containing perfluoro-n-alkanes (PFA) (aliphatic perfluoroalkanes). In 11 of the commonly-used wax products, PFA-C16 was the predominant PFAS component. The authors also discussed that fluorine-containing ski waxes may also contain traces of PFCAs, and increased blood levels of a range of PFCAs in the blood of professional ski waxers had been detected.

Nilsson *et al.* (2013) also sampled ski technicians' exposures and found PFAS (8:2 fluorotelomer alcohol (FTOH) and PFOA) in the air of wax cabins was several orders of magnitude higher for this occupational group than those in typical ambient indoor air. It was also noted that 8:2 FTOH can undergo biotransformation to PFOA.

Kaiser *et al.* (2010) published research on potential exposure sources of perfluorinated carboxylic acids in a facility that manufactured both APFO and PFOA. During a 2-week period, air monitoring was conducted near a process sump. Results showed quantifiable levels of PFOA in air. Additionally, family members of occupationally-exposed workers have been shown to have higher exposure to PFAS via dust transfer as compared with family members of workers who did not have occupational exposures to PFAS (ATSDR, 2021).

The company 3M estimated occupational PFOA exposures for various on-site exposure scenarios that were based on monitoring information collected at its Decatur Facility in the US state of Alabama (ATSDR, 2021). Occupational exposure scenarios included groundskeeper / maintenance workers and construction / utility workers exposed to on-site soils, surface water and sediment. Estimated on-site exposure to PFOA ranged from  $3.2 \times 10^{-6}$  to 2.4 ng/kg/day, with the highest estimated exposure corresponding to construction/utility workers engaged in projects involving contact with soil from an on-site field. In the case of PFOA, the most effective way to control exposure was found to be the prevention of dust dispersion.

### **Aqueous Film-Forming Foam (AFFF): occupational use**

ATSDR (2021) summarised studies on occupational exposure to PFAS within firefighters using AFFF. The significant PFAS in relation to AFFFs are: legacy PFOS AFFF (manufactured in the US from the late 1960s through 2002); legacy fluorotelomer AFFF (contain some long-chain PFAS) (manufactured in the US from the 1970s until 2016); modern fluorotelomer (FTOH) AFFF (short-chain PFAS became the predominant fluorochemicals used for foam manufacture).



PFAS serum levels of a group of firefighters in California were compared with a control adult population. Levels of PFOA and PFOS were only slightly higher in the firefighter group, whereas PFDA concentrations in firefighters were up to three times greater than in the control population (ATSDR, 2021). In addition, De Silva *et al.* (2021) and references therein noted that elevated levels of PFNA and other long-chain PFCAs have been recorded in firefighters, as have PFOS and PFHxS; from the analysis of the latter, it was determined that the firefighters had been exposed to products manufactured using legacy PFAS.

Firefighter textiles are an additional pathway for exposure to PFAS (Peaslee *et al.*, 2020). Textiles used as firefighter turnout gear were found to have high levels of total fluorine (up to 2%), and individual PFAS were identified and measured on both new and used firefighting turnout gear.

### **Non-occupational exposure**

Perfluoroalkyls have been measured in various non-occupational exposure pathways: indoor air, outdoor air, dust, food, surface water and various consumer products (ATSDR, 2021). Possible exposure pathways have been proposed, but the relative importance of these pathways, including their association with the accumulation of perfluoroalkyls in blood, is unclear.

Dietary exposure is likely to be regarded as the primary non-occupational exposure pathway. Drinking water is potentially providing a dominant pathway for individuals utilising a point source-contaminated supply.

The indoor pathways specifically focus on air and dust inhalation and dust ingestion. There is also dermal exposure via contact with PFAS-containing materials found within the home, including from consumer goods. Details on non-occupational exposure pathways are discussed below.

### **Consumer goods**

PFAS are used in many consumer goods. These include, for example, stain- and water-repellent textiles (including carpets, clothing and footwear), non-stick products (such as cookware), polishes, waxes, paints, cleaning products and cosmetics/personal care products. The use and presence of these goods in homes results in known exposure to PFAS. ATSDR (2021) reported that individuals with prolonged use of perfluoroalkyl-containing products would be a population with potentially higher PFAS exposure levels.

Exposure to PFAS from consumer goods occurs primarily via the oral and inhalation routes (through indoor air and dust), which could account for up to 50% of the total PFAS intake (Sunderland *et al.*, 2019). Sunderland *et al.* discussed that humans are frequently exposed to PFASs via direct skin contact with personal care and consumer products containing them. A rat model was used to determine that dermal penetration can be long-lasting and contribute considerably to the body burden of

PFASs, especially for those with moderate hydrophobicity (renal clearance of PFASs decreased with increasing carbon chain length) due to their skin permeation and urinary excretion factors.

Additional research was required to establish the link between the PFAS concentrations in consumer products and the concentrations in dust, air and food and their overall contributions to human exposure. Recently, Abraham and Monien (2022) demonstrated that there could be significant uptake of a PFAA via transdermal absorption in humans from a sunscreen and that it is plausible that this route of exposure would contribute to the internal exposure to PFAA. Weatherly *et al.* (2023) demonstrated that alternatives to legacy PFAS compounds (carboxylic PFAS – C7, C6, C5) used in industrial and consumer products can be absorbed through the skin and they raised the question as to whether these compounds are a suitable alternative to legacy PFAS. Details of known broad declared uses of UK REACH registered PFAS that can be found within consumer products are detailed within table 2.1.2 (with additional OECD information within table 3.2.1). However, information regarding the full extent of the PFAS used within consumer products and the exposure implications are not fully understood and more evaluation is required.

### **Food packaging and contact products**

PTFE cookware may contain residual PFOA in the low µg/kg range, and food packaging may contain PFAS because of their grease-resistant properties. COT (2022) concluded that PFAS used for food contact products are likely to contribute to overall human exposures to these substances, but that the contribution is small compared with other sources of exposure (COT, 2022). COT (2022) noted, however, that there is a need to fully understand the direct health implications of PFAS in food packaging, and that more information was needed on the chemical migration levels, i.e., how much of the PFAS from food packaging is transferred to the food itself.

In a GB context, the Food Standards Agency (FSA) has recently been made aware that the vast majority of paper packaging manufactured in the UK by Confederation of Paper Industry member companies does not use PFAS. PFAS are now predominantly used only in specialist packaging that has particular technical requirements such as moisture or grease resistance, for example for use in microwaveable popcorn bags (COT, 2022).

### **Non-dietary exposure**

Indoor air and dust are assumed to be significant contributors to PFAS exposure.

#### **Air (indoor)**

Human exposure to PFAS can occur through the inhalation of indoor air and contact with other media (Trudel *et al.*, 2008). PFAS in consumer products can contaminate dust and air (Danish EPA, 2018; Goldenman *et al.*, 2019). General external environmental sources may also have an impact on internal domestic PFAS levels.

It has recently been reported that concentrations of PFAS in indoor air generally exceed those of outdoor air and therefore exposure via inhalation is mainly due to indoor air (COT, 2022). For all PFAS considered (combined), toddlers had the highest exposures via inhalation and seniors had the lowest exposures. For individual PFAS, all estimated exposures from indoor air calculated across all population groups for both average median and maximum concentrations were below the TWI. For all PFAS considered, toddlers had the highest exposures via inhalation and seniors had the lowest exposures.

De Silva *et al.* (2021) proposed that there was the potential for indoor exposure to PFAS via inhalation, ingestion of dust and dermally. They suggested that investigation of indoor exposure to PFAS was more complicated than for many groups of compounds (e.g., polybrominated diphenyl ethers) because of the vast variety of physical–chemical properties of PFAS and the existence of precursors and polymers. It was detailed that some PFAS, such as FTOH and perfluorooctane sulfonamidoethanol, are relatively volatile and are found in the vapour phase indoors. Other PFAS, such as PFOA and PFOS, are found at high concentrations in dust. There was stated to be little information about the indoor presence and fate of fluorinated polymers (e.g., side-chain fluoropolymers used in some stain-resistance formulations), largely because of analytical limitations.

### Dust

Exposures from household dust (covering PFOS, PFOA, PFHxS and PFNA) at average median PFAS concentrations for all combined UK populations are estimated to be below the TWI for individual PFAS (COT, 2022). For exposures calculated from average maximum PFAS concentrations in household dust, COT (2022) calculated that the TWI would be exceeded for PFOS, PFOA and PFHxS by infants, toddlers and children.

## **Indirect exposure / intake of humans via the environment**

### Outdoor Air

Perfluoroalkyl levels have been measured in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean. Levels of PFOA, PFHpA, PFNA, PFDA, PFUnA, PFDoDA, PFOS, PFBS, PFHxS and FOSA were analysed (ATSDR, 2021).

Mean PFOA levels ranged from 1.54 to 15.2 pg/m<sup>3</sup> in air samples collected in the urban locations in Albany, New York; Fukuchiyama, Japan; and Morioka, Japan and in the rural locations in Kjeller, Norway and Mace Head, Ireland. Higher mean concentrations (101–552 pg/m<sup>3</sup>) were measured at the urban locations in Oyamazaki, Japan and Manchester, United Kingdom, and semi-rural locations in Hazelrigg, United Kingdom. Maximum reported concentrations at Oyamazaki and Hazelrigg were 919 and 828 pg/m<sup>3</sup>, respectively. ATSDR (2021) attributed the

elevated concentrations at the Hazelrigg location to emissions from a fluoropolymer production plant located 20 km upwind of this semirural community. The original GB monitoring is referenced in Section 3.1.3.

### Dietary exposure

Dietary exposure is assumed to be the main pathway for non-occupational exposure. The key routes of dietary exposure are from the consumption of meat/fish from animals and plants that have accumulated PFAS. Diet (particularly seafood, meat, and dairy) is a major source of human exposure to PFAAs. Sources of pre-PFAAs to the food-chain are difficult to constrain owing to potential contributions from pre-PFAAs in the food itself, as well as in packaging and wrapping (McDonough *et al.*, 2022).

Fish consumption presents a significant dietary exposure source for PFAS that bioaccumulate in food webs. In recreational fish species collected from surface waters across New Hampshire, US, analysis suggests that many precursors below detection in water have a higher bioaccumulation potential than their terminal PFAA. Perfluorobutane sulfonamide (FBSA), a short-chain precursor produced by electrochemical fluorination, was detected in all fish samples analysed for this substance (Pickard *et al.*, 2022).

The COT (COT, 2022) has made statements on the EFSA CONTAM Panel opinion on the risks to human health related to the presence of perfluoroalkyl substances in food (EFSA CONTAM Panel, 2020) and these are referred to throughout the section below.

For general dietary exposure, COT reported that EFSA had included UK exposure data (COT, 2022). UK lower bound mean exposures for adolescents, adults, the elderly and the very elderly approximated to the TWI. The exposures for other children (excluding adolescents) were approximately 2-fold the TWI. Toddler exposures calculated using the NDNS survey data were approximately 4-fold the TWI. Infant and toddler exposures estimated using the Diet and Nutrition Survey in Infants and Young Children (DNSIYC) survey data were approximately 14- and 7-fold the TWI (COT, 2022).

### Drinking water

PFAS have been found in groundwater, and in the raw water of drinking water supplies on a global scale. However, the highest impacts are usually associated on, or near, industrial and other sites with a history of PFAS use e.g., fire-fighting or training facilities such as airport sites or military bases. Whilst there may be PFAS found in actual drinking water in certain countries, the incidences at a UK level are isolated. A small number of abstractions that are known to be contaminated from known sources have been identified. Data are still being gathered regarding the extent of diffuse PFAS contamination and further data will be available as the

sampling programme develops. In these instances, water treatment, blending and granulated activated carbon (GAC) filters are used mitigating processes to limit final water concentrations (Personal Communication, DWI and Environment Agency, 2022).

Exposure to PFAS via drinking water from public water and private water systems is typically localised and associated with a release from a specific facility (e.g. manufacturer, processor, landfill, wastewater treatment, or facilities using PFAS-containing fire-fighting foams). There are a small number of abstraction sites in the UK which are contaminated from known sources, e.g. airports or historic fires. Data are being gathered at these sites regarding the extent of diffuse PFAS, and as analytical methods development improves, a more detailed picture will be produced (DWI, personal communication 2023).

PFAS are globally widespread at various levels in drinking water and groundwater (especially on and near industrial sites and, for example, fire-fighting facilities on military bases). Exposure to PFAS in the general population is thought to be at lower levels compared with those affected by occupational exposure or localised contamination (ATSDR, 2021).

Communities in the USA located near fluorochemical facilities, were reported to be at potential risk of higher PFAS exposures: PFOA, PFOS, PFBA, PFBS, PFNA and PFHxS have been detected in the municipal drinking water and private wells of some communities located near fluorochemical facilities (ATSDR, 2021).

COT (2022) stated that the Drinking Water Inspectorate suggested that trigger concentrations for further monitoring should be used for PFOS and PFOA for drinking water.

The Drinking Water Inspectorate (DWI) has issued guidance to the water industry on PFAS, using a risk based approach and a tiered system of actions based on sampling results. The Drinking Water Inspectorate is working with water companies to understand the risk to supplies from PFAS (DWI, 2021).

WHO have recently published a background document for the development of guideline standards PFOS and PFOA in drinking water, of 0.1 µg/l and total PFAS of 0.5 µg/l. These values are being reviewed by UK government stakeholders against environmental concentration data.

### 3.2.2 Vulnerable populations

During early development, children may be particularly sensitive to the harmful effects of PFAS. As well as being exposed during childhood, children can be exposed to PFAS *in utero* during pregnancy and via breast milk and formula milk (prepared with PFAS-contaminated water).

European average median PFAS concentrations in breast milk have been reported by the EFSA CONTAM Panel (2020); COT (2022) was not able to locate any UK data on PFAS levels in breast milk. COT therefore used European data with samples collected after 2008 to calculate exposures for UK infants aged 0 - <4 months and 4 - <6 months. The estimated breast milk exposures for UK infants exceeded the TWI, although COT (2022) clarified that the EFSA CONTAM Panel (2020) had stated that “the higher exposure of breastfed infants is taken into account in the derivation of the TWI and the intake by infants should therefore not be compared with this TWI”. EFSA also noted that breast milk exposures were very conservative and that one of the data-sets used could have skewed exposure estimates.

### 3.2.3 Human biomonitoring data

PFAS has been included in the list of chemicals of concern in the European Human Biomonitoring (HBM4EU) / Health Protection Unit (HPRU) study (HBM4EU, 2022). General population samples of blood and urine are being collected in collaboration with the Health Survey for England. When the results become available in 2024, they will enable a comparison of exposure levels in England with those in other countries, derivation of a UK background reference value, and evaluation of the impact of chemical regulation at one time point. Additionally, the European, Horizon Europe-funded Partnership for the Assessment of Risks from Chemicals (PARC; ANSES, 2022), which commenced in May 2022, will address PFAS; it will look at past and current exposures, develop new analytical methods and gather data from across Europe. Besides assessing human exposure, PARC will investigate environmental contamination / hot spots.

Until these data are available, there is European data on human exposures that can serve as a proxy for GB data (HBM4EU, 2022).

HBM4EU ‘aligned studies’ were conducted between 2014 and 2021 and applied a harmonised approach to collect samples and data from national studies that were representative of the European population across a geographic spread (Richterová *et al.*, 2023). The sampled population comprised European adolescents aged between 12 and 18 from sampling sites in Norway, Sweden, Greece, Slovenia, Spain, Slovakia, France, Belgium and Germany (total of 1957 samples collected). These data indicated that current internal exposure in teenagers exceeds the EFSA health-based guidance value (TWI) (EFSA CONTAM Panel, 2020) for the sum of four PFAS (PFOS, PFOA, PFNA and PFHxS) in 1.34% to 23.78% of the participants, depending on the different studies and locations (Bil *et al.*, 2023). Exceedance of the guidance value was most prevalent in western and northern Europe. PFOS was the dominant congener, with internal serum levels that were consistent with those reported in the EFSA opinion on the risks to human health related to perfluoroalkyl substances in food (EFSA CONTAM Panel, 2020). Overall, European data indicated that PFAS concentrations are in general higher in men with a trend for participants

with higher educational level to have higher exposure levels. In some studies, higher levels of PFAS were observed with increasing age.

Currently, time-trend studies to inform on differences in PFAS profiles at different times are not available at the European level. Time-trend data for the sum of PFOS, PFOA, PFNA and PFHxS are available from Germany and indicate that there has been a clear decrease in plasma levels of young adults from 2007 to 2019. Nevertheless, PFOS and PFOA were reported to still be the substances occurring in the highest concentrations in blood in Europe (HBM4EU, 2022). The EFSA opinion on PFOS and PFOA in food states that, generally, after the year 2000, the concentrations in serum/plasma of PFOS, PFOA and in some studies PFHxS have decreased, whilst the concentrations of PFNA, PFDA and PFUnDA have increased (EFSA CONTAM Panel, 2020).

Under the HBM4EU project, occupational PFAS exposure in chromate-plating facilities is also being investigated, with the analysis of 155 plasma samples of workers from five studies. The finding that workers undertaking chrome-plating activities might have been exposed to PFAS, including PFOS, led to the observation that exposure to PFAS in the metal industry requires attention in occupational safety and health practice (Santonen *et al.*, 2022).

### 3.2.4 Discussion of human exposure and biomonitoring

From a human-health perspective, PFAAs represent the original substances of concern (short-chain and long-chain PFCAs and PFSAs), along with their precursors (e.g. FTOH, FTSA, PFECA, PFESA etc.). This group also covers the substances that have undergone regulatory action (e.g. PFOA, PFOS, PFHxS etc.) (see Section 5). The majority of the data for human exposure is centred on PFOS and PFOA (COT, 2022).

COT (2022) stated that short-chain PFAS were found to have half-lives ranging from a few days (PFBA) to approximately 1 month (PFBS, PFHxA). However, PFHxS, PFOS, PFOA, PFNA, PFDA and PFUnDA have estimated half-lives that can exceed 3 years (and up to 8 years).

The greatest level of human monitoring and exposure data are available for PFOS and PFOA, their salts and precursors, which are regulated under the Stockholm Convention (UN POPs (2006) and UN POPs (2022a), respectively). Serum concentrations of these “legacy” PFAS in humans are declining globally, as shown by biomonitoring data, but total exposures to newer PFAS and precursor compounds that have replaced PFOS and PFOA with shorter chain lengths have not been well characterised. There is data, however, to indicate that serum/plasma concentrations of PFNA, PFDA and PFUnDA have increased since 2000. The most frequently identified PFAS by Sunderland *et al.* (2019) were the non-polymeric fluorotelomer-based substances, followed by non-polymeric PASF-based substances and PFAAs.

An individual's occupation and work activities can impact the specific PFAS they are exposed to, how much they are exposed to, and how they are exposed (as detailed by ATSDR (2021)). General studies have shown that certain occupations may have higher occupational exposure; these include chemical manufacturing workers; firefighters; ski wax technicians; carpet installers / treaters and waste handlers. Workers may be exposed to PFAS by inhaling them, getting them on their skin, and swallowing them, but inhaling them is the most likely route for exposure. However, worker exposure data is heavily biased towards legacy PFAAs that are now subject to global regulatory measures.

As noted, there is potential for human exposure to PFAS from FFF. Firefighters can be significantly exposed to PFHxS and other PFAS from firefighting foam via various occupational mechanisms (Rotander *et al.*, 2015).

Dietary exposure from food is assumed to be the dominant exposure pathway for the general population, although the indoor environment (dust, air) could account for up to 50% of the total PFAS intake (Sunderland *et al.*, 2019). Exposure via drinking water will also be important. Consumer products also represent a significant exposure potential to PFAS.

There is a particular importance to replace PFAAs (and their precursors) in: firefighting foams, processing aids for the polymerization of fluoropolymers and in the surface protection of textiles, apparel, leather, carpets and paper (Glüge *et al.*, 2020). Likewise, hydrofluorocarbons are used most frequently in the electronics industry. Alternatives to fluoropolymers will also be important in the production of plastic and rubber and in coatings, paints, and varnishes.

### **3.3 Discussion on environmental and human exposure**

We have provided an overview of potential exposure pathways of PFAS in the UK for the environment and humans. There are multiple sources identified that can be presumed as routes of primary exposure or drive environmental cycling, along with the widespread detection from GB environmental monitoring data. This includes prevalence of certain groups of PFAS and their transformation products (arrowheads) in many environmental compartments, e.g. soils, waters, sediment and the atmosphere; and also in wild biota, e.g. fish, air-breathing mammals and apex predators. GB exposures can be reasoned to be comparable to those seen on a global scale. As summarised by De Silva *et al.* (2021), the use of PFAS are widespread, covering personal care products, cosmetics, firefighting foams, textile treatments for stain and water repellence, food contact materials, medical devices and membranes in fuel cells, and for varied uses across many industries (Glüge *et al.*, 2020).

Current GB environmental monitoring data provides a snap-shot of specific PFAS based on targeted groups, many of which are inclusive of homologous substances, e.g. arrowhead PFAAs, or precursor FTOHs and FTS etc. Current monitoring



evidence is therefore only a partial picture of the number of PFAS present in the GB environment given monitoring occurs only for a small number of the total PFAS in use.

PFAS in the environment and humans are the result of external exposures to a much larger mixture of compounds, including precursors and transformation products. It is impossible to delineate arrowheads that are unique substances from those that are breakdown products of precursor substances, intermediate transformation products, impurities or intended mixture components of a commercial substance (Ankley *et al.*, 2021; Filipovic and Berger, 2015). Degradation / transformation rates of PFAS in the environment exceed decades in some cases, especially for the arrowhead substances (ITRC, 2022b). Neutral semi-volatile precursors such as FTOH and perfluoroalkane sulfonamide (FASA) can biotransform in humans and wildlife, contributing to overall exposures of the terminal end products such as PFOS and PFOA. Without considering precursors, intermediates and terminal transformation products, hazard, exposure and associated risk are likely underestimated. However, directly quantifying exposures to precursors is difficult because of *in vivo* biotransformation and the large number of unidentified compounds (Benskin *et al.*, 2009; Ross *et al.*, 2012; Yeung and Mabury, 2016).

The environmental monitoring currently reflects both past GB manufacturing and uses of PFAS, but also PFAS within articles imported from outside of GB. Examples of this include F-53B (a PFESA) and PFPA/PFPiAs. F-53B has been used widely as a replacement for PFOS, in chrome plating processes in Asia, and has since been detected in UK sediments, fish samples, air breathing organisms and waters (< LOD to low part per billion concentrations). PFPA/PFPiAs have been used as wetting or levelling agents in household cleaners and historically in US pesticide formulations (Lee and Mabury, 2017). They are noted to have similar physicochemical properties to the PFASs and are being detected in air-breathing terrestrial UK mammals and raptors. There are no UK or EU registrations relating to the PFPA/PFPiA or F-53B substances. Therefore, they are either being manufactured or imported at < 1 tonne/year per manufacturer/importer in the UK or they are being imported in articles in unknown quantities.

Where there are gaps in both the UK environmental monitoring datasets, comparisons can be made with other parts of the world where PFAS use patterns and emissions are likely to be similar. This applies in particular to northern Europe given geographical proximity and consistent chemical regulatory regime until January 2021. At an environmental compartment level these gaps include, but are not limited to, landfill leachates, soils that have been subject to application of biosolids or paper waste, irrigation, and atmospheric deposition; and uptake by plants (e.g. crops for human or animal food). Links between the environmental occurrence of PFAS and the human food chain have been documented. For example, PFAS contamination arising from the spreading of waste materials to land comes from Rastatt in Baden-Wuerttemberg, Germany. A large area of arable land

was affected following a long period of application of compost mixed with sludge from paper production. The paper sludge was contaminated with various PFAS that degraded to short-chain PFAS arrowheads in the soil, which were subsequently detected in groundwater at significant concentrations. This led to the closure of some abstraction points for drinking water, as well as the loss of crop growing potential because plants were found to exceed recommended maximum concentrations (Brendel *et al.*, 2018; Environment Agency, 2021).

At a human health level there are no long-term data relating to human samples originating in GB for any PFAS. Again, we can draw on data from Europe and the USA. Although these data are predominantly focussed on PFAS with identified toxicity concerns, it is only a small subset of PFAS identified in humans in comparison to the broader range of PFAS shown in environmental monitoring (Gebink *et al.* (2015a); Gebink *et al.* (2015b); Vestergren *et al.* (2008)). At country level there will be large variabilities across populations and PFAS compounds. Outside of occupational settings, diet is considered to be the major human exposure pathway for PFAS (De Silva *et al.*, 2021; Panieri *et al.*, 2022; Sunderland *et al.*, 2019), with drinking water identified as a major point-source of exposure especially for communities with contaminated water sources (De Silva *et al.*, 2021). In contrast, for the general population, as drinking water is remediated, exposures from dust (and soil), personal care products, indoor environments (inhalation of indoor air and dust) and other sources were considered more important.

ATSDR established that workers involved in making or processing PFAS and PFAS-containing materials are more likely to be exposed than the general population. It is clear that a worker's occupation and work activities can impact the specific PFAS they are exposed to, how much they are exposed to, and how they are exposed (as detailed by ATSDR, 2021). However, worker exposure data is heavily biased towards legacy PFAAs that are now subject to global regulatory measures. Additionally, in context, the numbers of people exposed occupationally are much smaller than consumers / general population.

### **3.4 Summary of exposure**

In conclusion, substances belonging to the following PFAS groups have been detected in the GB environment:

- PFECA and precursors
- Side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives
- Polyfluoroalkyl ether carboxylic acids
- PFESA and precursors
- PFFPA and PFFPiA and precursors

- PFCAs – short-chain and long-chain
- PFSAAs – short-chain and long-chain

These groups were amongst those prioritised for hazard assessment in this RMOA (Section 4).

There are no GB human biomonitoring data for the PFAS groups identified in the bullet points.

### 3.5 Key uncertainties and data gaps

A number of evidence gaps and uncertainties have been identified:

- There are thousands of PFAS chemicals in use as industrial and consumer chemicals. They have unique properties that make them challenging to analyse. The identification of ways to efficiently detect and measure a wide range of PFAS in environmental compartments and humans would improve our understanding of the extent of exposure.
- There is a ‘black-box’ associated with PFAS that are imported to GB in articles that do not have associated chemical safety data – for example there are no UK or EU registrations for PFPA and PFPiA substances or their precursors and yet they are being detected in liver tissues of terrestrial species. In the absence of registrants’ chemical safety data their physicochemical properties can be read across to PFSAs, many of which are under regulatory management. However, risk management will be hindered if all sources cannot be accurately identified.
- Even if sources of PFAS to the environment are stopped, environmental concentrations will decline very slowly. The long history of use of some PFAS means that there is a legacy of environmental contamination that is very hard to remediate.
- Interpretation of environmental monitoring data for PFAS requires acceptable limits - derived using toxicological data - against which we can assess potential risk to humans and the environment. Acceptable limits are yet to be derived beyond PFOS for environmental exposure in the UK.
- Ultimately, the limited exposure data for the majority of PFAS poses a significant challenge and a potential barrier to effective risk management.

## 4 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

The hazards of specific individual PFAS (and their salts), for example PFOA and PFOS, have been well investigated and recognised, resulting in various regulatory measures. This section aims to understand the potential hazards associated with the wider PFAS family at a group level. The following sections cover:

- The approach to the hazard assessment;
- The evidence of hazard for a key sub-set of the groups defined in Section 1 (Table 1.2.1);
- A summary of the human-health and environmental hazards of PFAS;
- Data gaps and uncertainties; and
- A discussion of the key outcomes of the assessment.

### 4.1 Approach

#### 4.1.1 Identification of groups

Because of the large number of substances in scope of this RMOA, the hazard assessment has focussed on a sub-set of the groups identified in Section 1, Table 1.2.1. The groups assessed are presented in Table 4.1.1. and include those:

1. With identified high tonnage uses/emissions based on Section 2, Table 2.3.1;
2. That contain substances that are manufactured at  $\geq 1$  tonne/year in GB (and so are registered under UK REACH) (Section 2.1);
3. That contain substances that have been detected in the GB environment (Section 3).

**Table 4.1.1: Groups identified for hazard assessment**

Group	Reason for assessment		
	High tonnage/use	Manufactured in GB	Detected in the GB environment
Perfluoroalkenes	Y	Y	
Polyfluoroalkyl substances: HFCs, HFEs and HFOs	Y	Y	
PFECAs and precursors		Y	Y
PFEs, epoxides and vinyl ethers		Y	
Perfluoroalkanes and perfluorocycloalkanes		Y	

Side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives			Y
Polyfluoroalkyl ether carboxylic acids			Y
PFESAs and precursors			Y
PFPA and PFPiA and precursors			Y
PFCAs and precursors – long-chain			Y
PFCAs and precursors – short-chain			Y
PFSAAs and precursors – short-chain			Y
PFSAAs and precursors – long-chain			Y

#### 4.1.2 Information sources

The assessment of hazard for the groups identified above collated information from the following sources:

- Substances with mandatory classification in the GB MCL list and technical reports in development;
- The relevant environmental and human-health data available within the EU REACH dissemination platform (ECHA, 2022b; accessed 2021/2022) for a minimum of five individual representative registered substances (see Annex VIII and Annex IX); The relevant environmental and human-health data available within the EU REACH dissemination platform (ECHA, 2022b; accessed 2021/2022) for a minimum of five individual representative registered substances (see Annex VIII and Annex IX);
- The relevant environmental data available within the US EPA CompTox® Chemicals Dashboard (US EPA, 2022b; accessed 2021/2022) for a minimum of five individual representative substances (see Annex VIII **Error! Reference source not found.**)<sup>2</sup>;
- Evidence from informal environmental assessments conducted by the Environment Agency on specific substances that were selected because they were either manufactured in GB or had been detected in the GB environment;
- Evidence from hazard and fate assessments conducted by other national authorities and international organisations.

<sup>2</sup> We did not consider human health data in CompTox® because an initial review found that the database referred back to the ECHA registration database for human health data and few additional data were available.

#### 4.1.3 Assessment of hazard: human health

The focus of the human-health hazard assessment was to determine if the T (toxic) criterion for effects on human health was met for any of the substances considered within the prioritised groups, to support conclusions on their PBT status<sup>3</sup>. Therefore, although all human-health hazard endpoints for which UK or EU REACH registration data were available were summarised in Annex IX, the main conclusions in this section pertain to the hazard categories listed in Section 1.3.3 of UK REACH Annex 13, namely:

- Carcinogenicity (category 1A or 1B)
- Germ cell mutagenicity (category 1A or 1B)
- Toxic for reproduction (category 1A, 1B or 2)
- Other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification for specific target organ toxicity (STOT RE category 1 or 2).

The assessments highlighted where a substance had a mandatory classification or registrants self-classified for one of the hazards above. The assessments also specified substances for which registration information indicated that they might meet one of the above hazard classifications; however, a formal hazard assessment, looking in detail at the individual studies, has not been performed.

#### 4.1.4 Assessment of hazard: environment

The following environmental hazards were considered:

- Persistent, Bioaccumulative and Toxic (PBT)
- Very Persistent and very Bioaccumulative (vPvB)
- Persistent, Mobile and Toxic or very Persistent and very Mobile (PMT or vPvM) (Hale *et al.*, 2022; UBA, 2021)<sup>4</sup>

The iterative process by which these environmental hazards are evaluated is shown in Annex VIII, Figure VIII-1.1. The parameters and threshold criteria used to assess the endpoints are summarised in Annex VIII, Table VIII-1.3.2.

Endocrine disruption was not considered within the review of the available data from the EU REACH registration platform and US EPA CompTox® Chemicals Dashboard (ECHA, 2022b; US EPA, 2022b); assessment of endocrine disruption generally relies on the weight-of-evidence approach, which was not possible using the high-

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<sup>3</sup> The criteria to identify substances as T (human-health) in a PMT assessment are identical to those defined in Annex XIII (UK REACH).

<sup>4</sup> The threshold criteria used are those that have been proposed since the publications of UBA (2021). These are discussed and detailed in Annex VIII

level review of these data. However, endocrine disruption was considered (in line with OECD (2018)) within the informal environmental risk assessments conducted by the Environment Agency, because those assessments considered all available data in greater depth. Endocrine disruption was not considered within the review of the available data from the EU REACH registration platform and US EPA CompTox® Chemicals Dashboard (ECHA, 2022b; US EPA, 2022b); assessment of endocrine disruption generally relies on the weight-of-evidence approach, which was not possible using the high-level review of these data. However, endocrine disruption was considered (in line with OECD (2018)) within the informal environmental risk assessments conducted by the Environment Agency, because those assessments considered all available data in greater depth.

## **4.2 Hazard information**

### **4.2.1 Classification**

#### **Mandatory classification in the GB MCL list and technical reports in development**

Screening of Annex VI of EU CLP (Regulation (EC) 1272/2008) to support the EU restriction of PFAS in fire-fighting foams identified 44 substances with harmonised classification for carcinogenicity, mutagenicity, reproductive toxicity (including effects on or via lactation) and specific target organ toxicity (STOT RE). This information is relevant to the UK as these substances all have equivalent mandatory classifications under GB CLP and are included in the GB Mandatory Classification and Labelling (MCL) list.

However, the substances identified as part of the screening exercise included several biocide and pesticide active substances with a single (isolated) -CF<sub>3</sub> group as part of a larger molecular structure. These substances have not been included in the group assessments of this RMOA and, as such, their classification is not considered further here.

PFAS identified with mandatory classification in the GB MCL list are summarised in Table 4.2.1.

**Table 4.2.1: Mandatory classification in the GB MCL list**

International Chemical Identification (as included in the GB MCL list)	EC No	CAS No	Classification
<b>Group: PFCAs and precursors – long-chain PFCAs</b>			
Perfluorooctanoic acid  (PFOA)	206-397-9	335-67-1	Carcinogenicity 2 Reproductive toxicity 1B (development) Effects on or via lactation Acute Tox. 4 Acute Tox. 4 STOT RE* 1 (liver) Eye Damage 1
Nonadecafluorodecanoic acid; [1]  Ammonium nonadecafluorodecanoate; [2]  Sodium nonadecafluorodecanoate [3]  (PFDA and its sodium and ammonium salts)	206-400-3 [1] 221-470-5 [2] [3]	335-76-2 [1] 3108-42-7 [2] 3830-45-3 [3]	Carcinogenicity 2 Reproductive toxicity 1B (development) Effects on or via lactation
Perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts  (PFNA and its sodium and ammonium salts)	206-801-3 [1] [2] [3]	375-95-1 [1] 21049-39-8 [2] 4149-60-4 [3]	Carcinogenicity 2 Reproductive toxicity (1B development, 2 fertility) Effects on or via lactation Acute Tox. 4 Acute Tox. 4 STOT RE 1 (liver, thymus, spleen) Eye Damage 1



Ammonium pentadecafluorooctanoate APFO (PFOA Ammonium salt)	223-320-4	3825-26-1	Carcinogenicity 2 Reproductive toxicity 1B (development) Effects on or via lactation Acute Tox. 4 Acute Tox. 4 STOT RE 1 (liver) Eye Damage 1
<b>International Chemical Identification</b>	<b>EC No</b>	<b>CAS No</b>	<b>Classification</b>
<b>PFSAs and precursors – long-chain PFSAs</b>			
Perfluorooctane sulfonic acid; Heptadecafluorooctane-1-sulfonic acid; [1] Potassium perfluorooctanesulfonate; Potassium heptadecafluorooctane-1-sulfonate; [2] Diethanolamine perfluorooctane sulfonate; [3] Ammonium perfluorooctane sulfonate; Ammonium heptadecafluorooctanesulfonate; [4] Lithium perfluorooctane sulfonate; lithium heptadecafluorooctanesulfonate [5]  (PFOS and the potassium, ammonium, lithium and diethanolamine salts)	217-179-8 [1] 220-527-1 [2] 274-460-8 [3] 249-415-0 [4] 249-644-6 [5]	1763-23-1 [1] 2795-39-3 [2] 70225-14-8 [3] 29081-56-9 [4] 29457-72-5 [5]	Carcinogenicity 2 Reproductive toxicity 1B (development) STOT RE 1 Acute Tox. 4 * Acute Tox. 4 * Effects on or via lactation Aquatic Chronic 2

\*STOT RE = specific target-organ toxicity - repeated exposure

A GB MCL Agency opinion is available for PFHpA<sup>5</sup> (Table 4.2.2), which is in the short-chain PFCAs group.

A GB MCL technical report is available for 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (6:2 FTOH)<sup>5</sup>, representing the group 'polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H and O'. This substance was identified during monitoring (Section 3) but the group was not identified as a

<sup>5</sup> GB MCL publication table: [publication-template.xlsx \(live.com\)](#)

priority group based on monitoring for hazard assessment, as it was captured under PFCAs and precursors.

Note that, to date, PFHpA and 6:2 FTOH are not included in the GB MCL list.

**Table 4.2.2 Classifications proposed to be added to the GB MCL list in Technical Reports and Agency opinions**

International Chemical Identification	EC No	CAS No	Classification
3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluorooctan-1-ol (6:2 FTOH)	647-42-7	211-477-1	STOT RE 2 (teeth, bones) Aquatic Chronic 1
Perfluoroheptanoic acid (PFHpA)	375-85-9	206-798-9	Reproductive toxicity 1B (development) STOT RE 1 (liver)

**Harmonised classification in Annex VI of EU CLP and proposals for harmonised classification**

The current EU harmonised classifications for the substances identified in Table 4.2.1 are the same as those given in the GB MCL list.

**4.2.2 Additional hazard information**

EU REACH registration (environment and human health) and CompTox® (environment only) data were initially collated for the groups identified based on tonnage/use and their arrowhead groups, that is:

- Perfluoroalkenes
- Polyfluoroalkyl substances: HFCs, HFES and HFOs
- PFCAs and precursors – short-chain
- PFCAs and precursors – long-chain
- PFSA and precursors – short-chain
- PFSA and precursors – long-chain

Heatmaps of the data availability for each of these groups and, where data were available, whether thresholds were exceeded are presented below (Figure 4.2.1-4.2.4). More information on the data available is presented in Annexes VIII (environment) and IX (human health).

Figure 4.2.1 Heatmap showing data availability and potential persistence at group level

RMOA Grouping	LAB DERIVED												MODELLED											
	Ready biodegradability		Inherent biodegradability		P				vP				Ready biodegradability		Inherent biodegradability		P				vP			
	< 70% DOC or < 60% O2/CO2	< 70% DOC (7d) or < 70% O2 (14 d)	Transformation in freshwater/estuarine overlying water	Transformation in marine overlying water	Transformation in freshwater/estuarine sediment	Transformation in marine sediments	Transformation in soil	Transformation in freshwater/estuarine overlying water	Transformation in marine overlying water	Transformation in freshwater/estuarine sediment	Transformation in marine sediments	Transformation in soil	Transformation in freshwater/estuarine overlying water	Transformation in marine overlying water	Transformation in freshwater/estuarine sediment	Transformation in marine sediments	Transformation in soil	Transformation in freshwater/estuarine overlying water	Transformation in marine overlying water	Transformation in freshwater/estuarine sediment	Transformation in marine sediments	Transformation in soil		
>40d	>60d	>120d	>180d	>120d	>60d	>60d	>180d	>180d	>120d	< 70% DOC or < 60% O2/CO2	< 70% DOC (7d) or < 70% O2 (14 d)	>40d	>60d	>120d	>180d	>120d	>60d	>60d	>180d	>180d	>120d			
Perfluoroalkenes	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	0	1	1	0	0	0	0	1	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

<b>KEY:</b>
All data above/below threshold (5)
Average data above/below threshold (4)
Max/min only data above/below threshold (3)
No data above/below threshold (2)
Only data available for 1 substance (1)

Figure 4.2.2 Heatmap showing data availability and potential bioaccumulation/mobility at group level<sup>1</sup>

RMOA Grouping	LAB DERIVED								MODELLED							
	Aquatic				Terrestrial				Aquatic				Terrestrial			
	B	vB	B	-	-	M	vM	B	vB	B	-	-	M	vM		
	Log <sub>Kow</sub>	BCF	BCF	BMF	Log <sub>Kow</sub>	Log <sub>Kow</sub> (Not expected to see lab data)	Log <sub>Koc</sub>	Log <sub>Koc</sub>	Log <sub>Kow</sub>	BCF	BCF	BMF	Log <sub>Kow</sub>	Log <sub>K<sub>ow</sub></sub>	Log <sub>Koc</sub>	Log <sub>Koc</sub>
>4.5	>2000	>5000	>1	>2	>5	<3	<2	>4.5	>2000	>5000	>1	>2	>5	<3	<2	
Perfluoroalkenes	1	0	0	0	1	0	0	0	3	3	2	0	4	2	3	2
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	3	4	2	0	4	0	4	3	3	2	2	0	4	2	4	4
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	2	3	2	0	5	0	0	0	5	3	2	0	5	2	2	2
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	2	0	0	0	3	0	5	5	2	2	2	0	3	2	4	4
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	3	2	2	0	5	0	0	0	3	2	2	0	5	2	4	4
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	2	2	2	0	2	0	1	1	2	2	2	0	3	2	5	4

KEY:
All data above/below threshold (5)
Average data above/below threshold (4)
Max/min only data above/below threshold (3)
No data above/below threshold (2)
Only data available for 1 substance (1)

<sup>1</sup>Note - data for the PFSAs and PFCAs should be considered cautiously due to surface active properties (see Appendix VIII).

Figure 4.2.3 Heatmap showing data availability and potential toxicity (environmental endpoints) at group level

RMOA Grouping	LAB DERIVED						MODELLED							
	Aquatic			Terrestrial	Aquatic			Terrestrial						
	Acute E(L)C50		Chronic NOEC or EC10		Acute E(L)C50		Chronic NOEC or EC10							
	<0.1 mg/L		<0.01 mg/L		<0.1 mg/L		<0.01 mg/L							
Fish	Daphnia	Alga	Fish	Daphnia	Alga	Plant/Earthworm/Microorganism/Avian	Fish	Daphnia	Alga	Fish	Daphnia	Alga	Plant/Earthworm/Microorganism/Avian	
Perfluoroalkenes	1	1	1	0	0	1	0	1	1	1	0	0	0	1
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	2	3	3	1	2	2	0	2	2	2	2	2	2	0
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	2	2	0	3	3	2	DA	0	0	0	0	0	0	0
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	2	1	2	2	1	2	1	2	2	2	2	2	2	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	2	1	1	3	3	0	DA	0	1	1	0	0	0	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	2	2	2	2	2	2	1	2	1	1	2	1	1	0

KEY:
All data above/below threshold (5)
Average data above/below threshold (4)
Max/min only data above/below threshold (3)
No data above/below threshold (2)
Only data available for 1 substance (1)
DA - data available and discussed in Annex VIII

Figure 4.2.4 Heatmap showing data availability and potential toxicity (human health endpoints) at group level

RMOA Grouping	LAB DERIVED																					
	Acute toxicity (oral)			Acute toxicity (dermal)			Acute toxicity (inhalation) (G = Gas, V = Vapour, A = Aerosol)			Repeated-dose toxicity (oral)	Repeated-dose toxicity (dermal)	Repeated-dose toxicity (inhalation), G = Gas (ppm), V = Vapour (mg/L), A = Aerosol	Skin irritation / corrosion	Eye irritation	Skin sensitisation	Mutagenicity	Sexual function and fertility	Developmental toxicity	Carcinogenicity	Endocrine disruption		
	< 50 mg/kg bw	50 - 300 mg/kg bw	300 - 2000 mg/kg bw	< 200 mg/kg	200 - 1000 mg/kg	1000 - 2000 mg/kg	100 < ATE ≤ 500 ppm (G), 0.5 < ATE ≤ 2.0 (V), 0.05 < ATE ≤ 0.5 (A)	500 < ATE ≤ 2500 ppm (G), 2.0 < ATE ≤ 10.0 (V), 0.5 < ATE ≤ 1.0 (A)	2500 < ATE ≤ 20000 ppm (G), 10.0 < ATE ≤ 20.0 (V), 1.0 < ATE ≤ 5.0 (A)	≤ 10 mg/kg bw/day (90 day) or ≤ 30 mg/kg bw day (28 day)	≤ 100 mg/kg bw/day (90 day) or ≤ 300 mg/kg bw day (28 day)	≤ 20 mg/kg bw/day (90 day) or ≤ 60 mg/kg bw day (28 day)	≤ 200 mg/kg bw/day (90 day) or ≤ 600 mg/kg bw day (28 day)	90day: ≤ 50 (G), ≤ 0.2(V), ≤ 0.02 (A), 28 day: ≤ 150 (G), ≤ 0.6(V), ≤ 0.06 (A)	90day: ≤ 250 ppm (G), ≤ 1.0(V), ≤ 0.2 (A), 28 day: ≤ 750 ppm (G), ≤ 3.0(V), ≤ 0.6 (A)	-	-	-	-	-	-	
Perfluoroalkenes	0	0	1	0	0	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	0	0
Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)	2	2	2	2	2	2	2	2	2	3	4	0	0	2	2	2	2	2	2	2	0	0
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Long chain PFCAs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Perfluoroalkyl carboxylic acids (PFCA) and precursors - Short chain PFCAs	2	2	3	0	0	0	1	1	1	5	5	0	0	0	0	4	4	3	2	2	2	1
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Long chain	1	1	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0
Perfluoroalkyl sulfonic acids (PFSA) and precursors - Short chain	4	4	5	2	3	3	0	0	0	2	2	0	0	0	0	4	4	2	2	2	2	0

Quantitative endpoints calculated by % occurrence below threshold value/ Qualitative endpoints (binary output endpoints) calculate the proportion of positives vs negatives for each group, a larger % positive occurrence will represent greater severity. Reproductive toxicity assessed on the basis of meeting the classification criteria (as outlined by the registrant).

**KEY (Quantitative endpoint key / Qualitative endpoint key):**  
 66% - 100% data below this threshold / 66%-100% positive occurrence (5)  
 33% - 66% data below this threshold / 33 - 66% positive occurrence (4)  
 0 - 33% of compounds below this threshold / 0 - 33 % positive occurrence (3)  
 No data below this threshold / > 1 compound but only negative results (2)  
 Only 1 compound in group with data (1)  
 No data (0)

It is emphasised that these heatmaps are based purely on the data sourced from the EU REACH registration data base and US EPA CompTox® Chemicals Dashboard for a select number of representative substances in each group; the heatmaps do not consider data from other sources.

The perfluoroalkenes group and HFCs, HFEs and HFOs group were expected to be the most data rich, since they contained substances with the highest tonnages, and hence had the greatest information requirements under EU REACH. However, given that it was not possible to draw firm conclusions on the hazards of the substances in these groups or their arrowhead groups from the ECHA registration and CompTox® data, the available ECHA registration or CompTox® data were not considered for the remaining groups.

Hazard information available in the informal environmental assessments and assessments performed outside the UK is described in Annexes VIII and IX and summarised below. Assessments were available for substances in the following groups:

#### Informal environmental risk assessments

- Perfluoroalkenes
- Polyfluoroalkyl substances: HFCs, - HFEs, HFOs
- PFECAs and precursors
- PFEs, epoxides and vinyl ethers
- Perfluoroalkanes and perfluorocycloalkanes
- PFESAs and precursors

#### Assessments performed outside the UK

- Polyfluoroalkyl substances: HFCs, HFEs, HFOs
- PFECA and precursors
- PFCAs – short-chain
- PFCAs – long-chain
- PFSAAs - short-chain
- PFSAAs – long-chain

### 4.2.3 Summary of hazards to human health

The arrowhead PFAAs are the most well-studied sub-class of PFAS in terms of their human-health effects. The body of knowledge on precursors in relation to, for example, toxicokinetics and health effects, is relatively small. Several arrowhead substances are listed in Table 4.2.1, meaning that they have mandatory

classifications in GB. Classifications amongst these substances that are relevant to the T criterion are reproductive toxicity, carcinogenicity and repeated-dose toxicity. These classifications are largely based on adverse effects noted in animals. Whilst many epidemiology studies have evaluated possible associations between PFAS exposure and various adverse health outcomes, most of these have focused on PFOA and/or PFOS (ATSDR, 2021). The US EPA recently compiled a systematic evidence map of epidemiology evidence of 150 PFAS, concluding that for most of the substances there was little to no data from humans to inform the evaluation of potential health effects (Radke *et al.*, 2022).

ATSDR (2021) reported that there are no specific biomarkers of effect for PFAS.

### **Toxicokinetics**

In its toxicological review of 12 perfluoroalkyl substances, the ATSDR (2021) reported that these substances are absorbed by all routes of exposure, with quantitative estimates for oral absorption in animals ranging from > 50% for PFHxS to > 95% for PFOA, PFBA, PFNA, PFDeA, PFUnA and PFDoDA. They are widely distributed in the body; the highest concentrations occur in the liver, kidneys and blood. They can also be transferred to the foetus during pregnancy and to infants via breast milk. These perfluoroalkyl substances do not appear to be metabolised or undergo chemical reaction in the body, irrespective of their chain length (ATSDR, 2021). Elimination of both PFCAs and PFSA is slower in male rats than in female rats (EFSA CONTAM Panel, 2020). They are primarily excreted into the urine (especially PFCAs with carbon chain length <10; EFSA CONTAM Panel, 2020), with smaller amounts eliminated in the faeces and breast milk (the EFSA CONTAM Panel (2020) reported that faecal excretion was the predominant route for PFSA, PFUnDA, PFDoDA, PFTrDA and PFTeDA). Enterohepatic recirculation can be extensive, for example for PFOA and PFOS.

Elimination half-lives in humans vary from hours to years, depending on the particular substance (for example, estimates for PFOA are 2.1-8.5 years, for PFOS 3.1-7.4 years and for PFHxS 4.7–15.5 years). IARC (2016) reported that, uniquely to humans, PFOA is highly efficiently reabsorbed in the kidneys compared with other studied animals, which leads to much longer retention in the human body. Consequently, the body burden of PFOA in humans is much greater than in experimental animals.

In their review of biotransformation pathways of fluorotelomer-based polyfluoroalkyl substances, Butt *et al.* (2014) summarised toxicokinetic studies on 8:2 FTOH (which is the substance used in most of these investigations). The studies indicated rapid biotransformation to PFOA and, to a lesser extent, PFNA and shorter chain-length PFCAs. The yield of PFOA and PFNA was generally low but increased in a time- and dose-dependent manner, consistent with their long half-lives in mammals.



### **Acute toxicity, irritation, skin sensitisation**

Several of the arrowhead substances listed in Table 4.2.1 have mandatory classifications for acute toxicity following single oral and/or inhalation exposures and/or for eye damage.

Information on acute toxicity, skin and eye irritation and skin sensitisation of the REACH-registered substances that were assessed is provided in Annex IX.

Hexafluoropropene (perfluoroalkene group) has a harmonised classification for acute toxicity by the inhalation route (Category 4), whilst several substances in the short-chain PFCAs, long-chain PFSA and short-chain PFSA groups met the classification criteria for acute oral or dermal toxicity. Some substances were skin corrosive and eye irritant / damaging (short-chain PFCAs, short-chain PFSA groups). Apart from one substance (ammonium perfluorohexanoate), none of the substances showed a skin sensitisation potential.

### **Repeated-dose toxicity**

All but one of the substances listed in Table 4.2.1 has a mandatory classification for specific target-organ effects following repeated exposure (STOT RE). The target organs following repeated exposure of experimental animals are typically the liver and kidney. Altered thyroid hormone levels are reported with exposure to some substances (COT, 2022). PFOS and PFOA have been reported to cause immunotoxicity in animals.

Where adverse effects were reported in repeated-dose toxicity studies with the registered substances that were assessed, the liver and kidneys were also the target organs. For example, exposure to hexafluoropropene (perfluoroalkene group) caused microscopic changes to the kidneys of experimental animals at concentrations that are relevant for classification. The main target organ of lithium bis(trifluoromethylsulfonyl)imide (short-chain PFSA) in animals was the liver; this substance has a mandatory classification for STOT RE. Associations between PFAS exposure and liver function/disease in humans are inconsistent or only modest, whilst an association with kidney function has not been demonstrated (COT, 2022). Because of their registered tonnages, no or limited information was available on the repeated-dose toxicity of several registered substances.

### **Genotoxicity**

Genotoxicity has not been highlighted as a potential concern for PFAS. The available information as reviewed by EFSA (EFSA CONTAM Panel, 2018, 2020) indicates that PFOS and PFOA might cause oxidative stress but there is no evidence that they have a direct genotoxic effect (COT, 2022); by extension, because of structural similarity with PFOA and PFOS, respectively, PFNA and PFHxS are unlikely to have a direct genotoxic mode of action. The CONTAM Panel concluded that the study and data availability are limited for other PFAS.

Many of the registered substances included in the current hazard assessment had been tested in various *in vitro* and, occasionally, *in vivo* tests. None of these nor the substances for which an informal environmental assessment was undertaken showed a genotoxic potential.

### **Carcinogenicity**

Whilst carcinogenicity has been raised as a concern for PFAS, no substance has been established as a human carcinogen. Several substances (PFOA, APFO, PFDA and PFNA and their sodium and ammonium salts, from the long-chain PFCAs group; PFOS and its potassium, ammonium, lithium and diethanolamine salts) have mandatory classifications for carcinogenicity in Category 2, meaning that there is some evidence that they cause cancer in laboratory animals and/or humans, but that the information is insufficient to reach a firm conclusion on whether they are human carcinogens.

IARC concluded that PFOA is possibly carcinogenic to humans; this conclusion was based on limited evidence in humans (noting that there was a positive association for cancers of the testis and kidney) and limited evidence in experimental animals (IARC, 2016). The EFSA CONTAM Panel (2018) opinion on PFOS and PFOA concluded that the available epidemiology studies provided insufficient evidence to state that either substance was a carcinogen in humans, which the panel noted was consistent with the IARC report of limited evidence for carcinogenicity in humans. The EFSA CONTAM Panel (2020) reviewed additional epidemiology data published since the 2018 opinion, comprising studies on other PFAS and one study on PFOS and PFOA. The Panel concluded that its previous conclusion on PFOS and PFOA still applied, whilst limited information was identified for the other PFAS. After reviewing the EFSA CONTAM Panel (2020) opinion, the COT (2022) concluded that the information published since 2018 did not provide any evidence of a link between PFOS, PFOA or other PFAS exposure and cancer risk.

COT (2022), summarising the information considered by the EFSA CONTAM Panel (2018), reported that PFOS and PFOA were tumour promoters in rodent livers and that PFOA might also induce Leydig cell tumours in rats. PFHxA was not carcinogenic in a long-term study in animals, whilst PFNA and PFDA, but not 8:2 FTOH, showed tumour-promoting activity in a model system. There was no information for the other substances considered in the EFSA opinion.

Of the REACH-registered substances considered, ammonium perfluorohexanoate, was not carcinogenic in a standard study in rats. The registrants of tetraethylammonium perfluorooctane sulfonate applied a read-across approach from data on the potassium salt of PFOS; consequently, they apply a self-classification for carcinogenicity (Category 2). None of the registration dossiers for the other substances assessed contained carcinogenicity studies, nor were carcinogenicity studies available for most of the substances for which an informal environmental assessment was undertaken.

## **Reproductive toxicity**

Amongst the arrowhead substances in Table 4.2.1, PFOA, PFDA and its sodium & ammonium salts, PFNA and its sodium & ammonium salts, APFO (ammonium salt of PFOA) (all members of the long-chain PFCAs group), PFOS and its potassium, ammonium, lithium and diethanolamine salts (members of the long-chain PFSA group) are classified in Category 1B for reproductive toxicity (specifically, adverse effects on development), meaning that they may damage the unborn child. They are presumed human reproductive toxicants: although there is no or insufficient evidence of them having caused malformations or other effects on development in humans, there is clear evidence that they have caused such effects in animals, with the presumption that the same effects could occur in humans. PFDA and PFNA plus their sodium & ammonium salts are also suspected of damaging fertility. In this case, they are suspected human reproductive toxicants: there is some evidence of an adverse effect in animals (or possibly humans), but this is less convincing than for presumed human reproductive toxicants.

Reproductive toxicity in animal studies has also been reported for other PFAS, including PFHxS (e.g., COT, 2022; EFSA CONTAM Panel, 2020). The observed effects of PFAS have included impaired normal development of mammary glands, delayed offspring growth and increased post-natal deaths, decreased sperm production, reduced numbers of offspring in the next generation and reduced litter size (COT, 2022). Findings can vary between the tested species: PFBS did not induce reproductive toxicity in rats when tested at a high dose (1000 mg/kg bw/d), but resulted in development and growth delays in mice that were exposed during gestation.

PFHxA has been reported to cause developmental toxicity (ECHA, 2019c); however, the study in which developmental toxicity was reported was a non-standard mouse study conducted with ammonium perfluorohexanoate, and no developmental toxicity was reported in standard rat studies with another related substance, sodium perfluorohexanoate. Therefore, further assessment of this data would be needed to conclude on this hazard.

The EFSA CONTAM Panel (2018) concluded that PFOA and PFOS caused developmental neurotoxicity in rodents. It has also been reported that PFDoDA can efficiently transfer into rat brain and cause cognitive behavioural changes (COT, 2022).

The COT (2022) recently summarised the observations of reproductive toxicity in humans, as reported by the EFSA CONTAM Panel (2018, 2020). EFSA concluded that 'there may well be a causal association between PFOS and PFOA and birth weight' (EFSA CONTAM Panel, 2018); it was not possible to make the same association for other PFAS. The ATSDR also concluded that the evidence suggested an association between PFOA and PFOS and small decreased in birth weight, but

noted that cause-and-effect relationships had not been established (ATSDR, 2021). There was insufficient information to indicate that PFAS were associated with other adverse development or reproduction outcomes in humans.

There are no UK or EU REACH registrations for long-chain PFCAs. One registered substance in the long-chain PFSA group was included in the current hazard assessment, tetraethylammonium perfluorooctane sulfonate. The registrants of this substance read-across toxicity information for reproductive toxicity from PFOS, and consequently self-classify for developmental toxicity (Repr 1B).

Information on reproductive toxicity (development and fertility) was available for most registered substances in the perfluoroalkenes, perfluoroalkyl substances: HFCs, HFEs, HFOs groups and short-chain PFSA groups; none of these caused reproductive toxicity in the available animal studies.

There are indications from a developmental toxicity study that trifluoroacetic acid (TFA) (short-chain PFCAs) might cause rare abnormalities in rabbit offspring. This is important because TFA is an arrowhead substance to which many PFAS can transform, such as those with isolated  $CF_3-$  moieties (which includes some substances used in pharmaceutical or biocide/pesticide applications).

The informal environmental assessment of EEA-NH4 highlights a potential concern for developmental toxicity on the basis of a self-classification for this end-point by the registrants. For the other substances subject to an informal environmental assessment, there was either no concern for reproductive toxicity or no reproduction or developmental toxicity studies were available.

### **Other effects**

PFOA and PFAS in humans have both been associated with reduced antibody response to vaccination in humans (EFSA CONTAM Panel, 2020), although COT noted that there are inconsistencies in the data (COT, 2022).

The EFSA CONTAM Panel concluded there was insufficient information to suggest that PFAS adversely affected neurobehavioural, neuropsychiatric and cognitive outcomes in humans, or that they were associated with allergy and asthma. The Panel also reviewed papers that looked at PFOS, PFOA and other PFASs in relation to endocrine effects in humans (thyroid function and disease, male fertility and puberty, female fertility, menstrual cycle and puberty) and concluded that the available evidence was insufficient to suggest that the PFAS exposures are associated with effects on these endpoints (COT, 2022). However, there do appear to be associations between PFNA and serum cholesterol levels. However, there do appear to be associations between PFNA and serum cholesterol levels.

Summary conclusions on the human-health hazards of most relevance to this RMOA for the groups for which information was available are presented below.

## Perfluoroalkenes

The registration information and informal environmental assessment of one substance, hexafluoropropene, indicated that the T criterion was met for this sub-group member. Information on reproductive toxicity (development and fertility) was available for most registered substances, none of which caused reproductive toxicity in the available animal studies. Genotoxicity information was limited (but negative), whilst there were no carcinogenicity studies for the assessed substances. No human-health hazard assessments outside the UK have been located.

### **Polyfluoroalkyl substances: HFCs, HFEs and HFOs**

There were no concerns for genotoxicity or reproductive toxicity for the assessed substances. Whilst liver effects were reported in the repeated-dose toxicity studies, these were likely to be adaptive changes rather than adverse effects. Informal environmental assessments of two substances concluded that the T criterion was not met for these sub-group members. There is no additional information on the potential human-health hazards of this subcategory from the identified non-UK reviews of PFAS.

### **PFCAs and precursors – long-chain**

Carcinogenicity and reproductive toxicity have been identified as human-health hazards for some members. PFOA, PFNA and PFDA, their salts and related substances have mandatory classifications for these hazards. Other cited human-health effects relate to liver toxicity, immunotoxicity and thyroid toxicity. Toxicity to PFOA and PFNA has been reported at relatively low levels of exposure (EFSA CONTAM Panel, 2020), although COT has attached strong caveats to this value (COT, 2022). There are no informal environmental assessments for this group.

### **PFCAs and precursors – short-chain**

The main potential concern identified for registered substances in this sub-group is developmental toxicity following exposure to trifluoroacetic acid (TFA). Other hazard assessments have identified concerns for developmental toxicity for some other members of the sub-group (undecafluorohexanoic acid (perfluorohexanoic acid or PFHxA) and related substances). There are no informal environmental assessments for members of this sub-group.

### **PFSA and precursors – long-chain**

The hazards of concern for this group are developmental toxicity, carcinogenicity and repeated-dose toxicity. PFOS and its potassium, ammonium, lithium and diethanolamine salts have mandatory classifications for these hazards. The human-health effects of the one REACH registered substance were assessed by read-across from PFOS (potassium salt). The Environment Agency has not undertaken an informal environmental assessment of substances in this group.

## PFASs and precursors – short-chain

Of the substances considered within this sub-group that have a REACH registration, lithium bis (trifluoromethylsulfonyl)imide has a mandatory classification for human-health effects (repeated-dose toxicity - STOT RE 2). None of the information submitted in registration dossiers for the other substances indicated concerns for repeated-dose toxicity, genotoxicity or reproductive toxicity. There was no information on carcinogenicity. In reviews of perfluorobutane sulfonic acid (PFBS) by the EU, Australia and the USA, the following adverse effects in rodents were reported: thyroid hormonal disturbances, reproductive toxicity, effects on the liver, kidney and haematological system. **The Environment Agency has not undertaken an informal environmental assessment of substances in this group.**

## PFECA and precursors

The REACH registrant of ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)-ethoxy]acetate (EEA-NH<sub>4</sub>, CAS no. 908020-52-0) self-classifies the substance for reproductive toxicity (Environment Agency, 2023c).

The other groups for which informal environmental assessments were performed had limited toxicity information.

### 4.2.4 Summary of hazards to the environment

The heatmaps (Figures 4.2.1-4.2.4) of the ECHA registration and CompTox® data for the groups identified in Section 4.2.2 show that there were indications that registered substances within each of the groups were persistent, bioaccumulative, mobile and/or toxic, but the data were often conflicting at group level. Neither the individual substances, nor the PFAS groups, met the definitive or screening hazard criteria for PBT, vPvB, PMT nor vPvM (see Annex VIII and Annex IX). **However, owing to the often limited amount of information on their environmental fate, behaviour, long-term aquatic toxicity and toxicity to humans, there is sufficient uncertainty to reserve judgment.**

As previously noted, the heatmaps were derived from data sourced solely from the EU REACH dissemination platform and US EPA CompTox® Chemicals Dashboard and do not consider data from other sources. Therefore, any conclusions that can be drawn demonstrate that data collated from these sources cannot be relied upon to draw definitive conclusions at the grouping level; for example, Figure 4.2.1 indicates that there are insufficient data to conclude on P/vP, but it is globally recognised that many PFAS are P/vP substances.

The identified environmental hazards of groups considered in informal environmental assessments and/or non-UK assessments are summarised below.

## Perfluoroalkenes

- Hexafluoropropene (CAS no. 116-15-4) is a gas, that is partially soluble in water, and screened as P or vP, had a low potential for B, met the draft vM criterion, and met the T criterion (Environment Agency, 2023f).

## Polyfluoroalkyl substances: HFCs, HFEs and HFOs

- 1H-perfluorohexane (CAS no. 355-37-3) screened as potentially P or vP, had a low potential for B (though there was uncertainty in the data) and did not meet the draft criteria for M, nor screen as T (Environment Agency, 2023h).
- Perfluorobutylethylene or PFBE (CAS no. 19430-93-4) screened as potentially P or vP, potentially vM, had a low potential for B (though there was uncertainty in the data), and did not screen as T (Environment Agency, 2023e).
- 2H-Tricosafuoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane or TFEE-5 (CAS no. 37486-69-4) was evaluated in the EU. The evaluating member state identified that the substance was vP, but could not definitively conclude on B or T, owing to a lack of data and uncertainty in the data (ECHA, 2020c).

## PFECA and precursors

- Ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)-ethoxy]acetate or EEA-NH<sub>4</sub> (CAS no. 908020-52-0) screened as potentially P or vP and had a low potential for B in fish, but it was not possible to draw a conclusion on its bioaccumulation potential in air-breathing organisms. It was considered likely to meet the draft criteria for M and vM and met the T criterion (Environment Agency, 2023c). An EU substance evaluation of EEA-NH<sub>4</sub> identified that the substance was very persistent and was mobile in soil and water; there were insufficient data to conclude on B (ECHA, 2020a).
- An EU substance evaluation of ammonium 2,2,3 trifluor-3-(1,1,2,2,3,3-hexafluoro-3-trifluoromethoxypropoxy), propionate or ADONA (EC number 480-310-4) identified that the substance was very persistent and mobile, but there were insufficient data to conclude on B (ECHA, 2020b)).

## PFE, epoxides and vinyl ethers

- 1,1,1,2,2,3,3-Heptafluoro-3-[(trifluorovinyl)oxy]propane or PPVE (CAS no. 1623-05-8) screened as potentially P or vP and did not screen as B or M (though there was uncertainty in the data). PPVE did not screen as T. It was noted that PPVE transforms to PFPA in the environment, which is expected to be vPvM (Environment Agency, 2023b).

## Perfluoroalkanes and perfluorocycloalkanes

- 1,1,1,2,2,3,3,4,5,5,5-Undecafluoro-4-(trifluoromethyl)pentane or PFiHx (CAS no. 355-04-4) screened as P or vP. PFiHx screened as B and potentially vB, but this was based on QSAR data and there was uncertainty whether the

substance was within the applicability domain of the model used. PFiHx screened as M. PFiHx did not screen as T, but there was an absence of reliable information (Environment Agency, 2023i).

- Perflunafene or PFD (CAS no. 306-94-5) screened as potentially P or vP and potentially B or vB. PFD did not screen as M (though there was uncertainty in the data) or T (but there was an absence of reliable information) (Environment Agency, 2023j).
- Octafluoropropane or PFP (CAS no. 76-19-7) screened as P or vP. It did not screen as B, but did screen as M (though there was uncertainty in the data). PFP did not screen as T (but there was an absence of reliable information) (Environment Agency, 2023a).

### **PFESA and precursors**

- F-53B (CAS No. 73606-19-6) screened as potentially P or vP, B or vB (based on non-standard data on bioconcentration in fish and monitoring data), M or vM, and T (Environment Agency, 2023g).

### **PFCAs – short-chain**

- PFHxA was identified as being vP, mobile in the aquatic environment, having long-range transport potential, potential to enrich in plants and meeting the T criteria (ECHA, 2019c).
- PFHpA was proposed to be identified as PBT and vPvB (currently under consultation in the EU) and also had mobile and long-range transport potential (ECHA, 2022c). An Australian review concluded that PFHpA and its direct precursors were P and had some potential for biomagnification in marine and terrestrial mammals (NICNAS, 2015f).
- PFCAs – short-chain and their precursors were concluded by Australia to be persistent and mobile and could become globally distributed, but were not B or T according to their criteria (AICIS, 2022; NICNAS, 2015a, 2019). The USA considered that short-chain PFCAs would exist as their anions in the aquatic compartment and would likely bioaccumulate in protein albumin; they concluded environmental persistence of the compounds, with resistance to biodegradation, direct photolysis, atmospheric photooxidation and hydrolysis (ATSDR, 2021).

### **PFCAs – long-chain**

- Long-chain PFCAs were concluded to meet the criteria for PBT and long-range transport potential under the Stockholm Convention on Persistent Organic Pollutants (currently going through Annex E nomination process) (UN POPs, 2022b, 2022c). The USA concluded that long-chain PFCAs would exist as their anions in the aquatic compartment and would likely bioaccumulate in protein albumin, with accumulation potential decreasing with chain lengths greater than



8 carbon units. They concluded environmental persistence of the compounds, with resistance to biodegradation, direct photolysis, atmospheric photooxidation, and hydrolysis (ATSDR, 2021).

- PFOA, its salts, and related compounds (C<sub>8</sub> homologue of the long-chain PFCAs) have been identified as POPs under the Stockholm Convention (UN POPs, 2022a) and by Australia (NICNAS, 2015e).
- C<sub>9</sub>–C<sub>14</sub> PFCAs, their salts, and precursors were concluded to be PBT (C<sub>9</sub> and C<sub>10</sub> PFCAs) and vPvB (C<sub>11</sub>–C<sub>14</sub> PFCAs), highly mobile in the aquatic environment and to have long-range transport potential, with evidence for their presence in remote areas (European Commission, 2021).
- C<sub>9</sub>–C<sub>20</sub> PFCAs, their salts, and precursors were concluded by Canada to be extremely persistent, with weight of evidence to conclude that they accumulate and biomagnify in terrestrial and marine mammals (Environment Canada, 2012; Government of Canada, 2022).
- PFNA was identified as PBT by the EU (ECHA, 2015a).

#### **PFSAs – short-chain**

- PFBS was concluded by the EU to have very high persistence, high mobility, high potential for long-range transport, moderate bioaccumulation in humans and to be toxic (ECHA, 2019b). Australia concluded that PFBS and its precursors were highly persistent and mobile, with the potential for global distribution (NICNAS, 2015d).
- Some of the C<sub>5</sub>–C<sub>7</sub> PFSAs were concluded by Australia to hydrolyse and/or dissociate into the perfluoropentanesulfonate anion (PFPeS); they concluded that the arrowhead anion was persistent, but considered there was insufficient information to determine if the anion was bioaccumulative or toxic (NICNAS, 2015c).

#### **PFSAs – long-chain**

- PFOS, its salts and perfluorooctanesulfanylfluoride (PFOSF) were concluded to be POPs under the Stockholm Convention (UN POPs, 2006). Canada concluded that PFOS, its salts, and precursors were extremely persistent and bioaccumulate in mammals and piscivorous birds (Environment Canada, 2006)
- PFHxS, its salts and related substances were identified as vPvB (ECHA, 2019a).
- PFSAs > C<sub>8</sub> and their direct precursors were concluded by Australia to be PBT according to their domestic criteria (NICNAS, 2015b). USA concluded on environmental persistence of the long-chain PFSAs (ATSDR, 2021).
- Some of the C<sub>5</sub>–C<sub>7</sub> PFSAs were concluded by Australia to hydrolyse and/or dissociate into the perfluoroheptanesulfonate anion (PFHpS) and the perfluorohexanesulfonate anion (PFHxS); they concluded that the arrowhead

anions were persistent and bioaccumulative, but considered that there was insufficient information to determine if the anions were toxic (NICNAS, 2015c).

### 4.3 Key uncertainties and data gaps

This high-level hazard assessment primarily relied on the following sources of information:

- EU REACH registration data (human health and environment)
- CompTox® data (environment only)
- Informal environmental assessments undertaken by the Environment Agency
- Assessments conducted by national authorities and international organisations

In summarising the human-health concerns of PFAS, other authoritative reviews were referenced. No literature searches were performed to address hazard end-points.

The human-health and environmental hazards of a relatively small number of PFAS have been well investigated and characterised, generally being those for which national or international assessments have been performed. These substances generally fall within the (long-chain and short-chain) PFCAs and PFSA groups.

There were clear data gaps for all PFAS groups considered. This was highlighted in both the informal environmental assessments, for which there was an absence of reliable information to conclude on PBT status for the substances in some groups, and in reviewing registration dossiers. Some substances selected for assessment were not registered and overall little was known about the toxicity and environmental properties of those substances. For substances that were registered, the information requirements varied depending on the substance's import and/or manufacturing tonnage, thus affecting the data available for this assessment. Furthermore, some registrants met their information requirements through read-across of data from other substances; not all the justifications for doing so were assessed as part of this hazard assessment, increasing the level of uncertainty in relation to some substances.

The unusual chemistry (e.g. surface activity, recalcitrance) of many PFAS makes them unsuitable for assessment in many standard studies (e.g., octanol water partition coefficients, water solubility, aerobic/anaerobic degradation studies). This is clearly demonstrated when considering bioaccumulation; existing metrics are not suitable for measuring PFAS accumulation in wildlife as they consider accumulation in storage lipids, whereas PFAS (specifically the PFAAs) are proposed to accumulate in biota and organs via protein- and phospholipid-driven mechanisms (De Silva *et al.*, 2021). Therefore, there is a high level of uncertainty in the reliability

of bioaccumulation endpoint data from standard OECD studies performed to fulfil the EU REACH registration requirements.

In addition, the volatility of those substances identified as F-gases, e.g. polyfluoroalkyl substances: HFCs, HFEs and HFOs, fall into the category of difficult to test substances. This is due to their increased potential to partition to air within standard study designs. There is therefore uncertainty in interpreting data for a substance does not fall within the applicability domain of the study design, resulting in a reduction in reliability of data. Data should therefore be treated cautiously as inherent volatility would be observed in the natural environment.

Additional environmental data that were available from the US EPA CompTox® chemicals dashboard were primarily *in silico* or modelled data. There are uncertainties around whether the reported values from some of the models were reliable, as it was beyond the scope of the high-level review to assess whether the substances fell within the applicability domains of the respective models. Owing to the unusual chemistry of PFAS, there is an absence of reliable and relevant data for inclusion into validation and test sets of *in silico* models. *In silico* predicted values should always be treated with caution where substances in the training set and external test sets are not visible. Much of the laboratory-derived and modelled data for the individual PFAS substances were inconsistent, demonstrating that the available modelled data might not be reliable.

Overall, therefore, there is uncertainty in the outcomes of the review of registration and CompTox® data. In addition, Figures 4.2.1 - 4.2.4 provide overviews of the environmental hazard and human-health hazard of the groups assessed and clearly show that in most cases there are no (grey) or insufficient (blue) data to conclude on a hazard.

Another key uncertainty is the assumption that five to eight substances can be used to infer group-level hazard. Although the groups were based on structural similarity, where data to inform on hazard endpoints were present for several of the representative substances, on several occasions those data spanned a large range within each group, creating ambiguity in drawing a definitive conclusion. This is touched upon in the exposure section and is also relevant to group-level hazard assessments. In brief, Ankley *et al.* (2021) cite an example of disparity in physicochemical parameters across a range of homologous PFAS from Krafft and Riess (2015). These authors present data demonstrating that for a homologous series of fluorotelomer alcohols with carbon chain lengths from 4 to 10, the experimental water solubility, air/water partition coefficient, octanol/water partition coefficient, octanol/air partition coefficient and organic carbon/water partition coefficients can vary by 2 to 5 orders of magnitude.

Whilst the informal environmental assessments conducted by the Environment Agency provided a more in-depth analysis of specific substances that are manufactured in the UK or detected in the UK environment, the substances

assessed did not span all the groups considered. For some of the groups (PFECA and precursors; perfluoroalkyl ethers, epoxides and vinyl ethers; PFESA and precursors), only one substance had been the subject of an informal review and registration / CompTox® data were not evaluated for the purposes of this RMOA, meaning that for these a group-level hazard assessment has not currently been undertaken.

There were no hazard data located in the described sources for three groups: side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives; polyfluoroalkyl ether carboxylic acids; and perfluoroalkyl phosphonic and phosphinic acids.

#### **4.4 Discussion**

The structural and physicochemical diversity of PFAS screened in this hazard assessment was broad, but still only a very small proportion of the total family. Across the three priority areas (tonnage/use, manufacturing in GB, detection in monitoring), only fourteen of the groups identified in Table 1.2.1 were considered for hazard assessment (not all to the same degree, as described above).

A wide variety of toxic effects have been associated with arrowhead perfluoroalkyl acids (PFAAs, i.e., the PFCAs and PFSAs) in experimental animals and, to a lesser extent, in humans. Most epidemiology studies have focused on PFOA and/or PFOS; for most other substances, there is little to no data from humans to inform the evaluation of potential health effects. Environmental hazards are also associated with many of these PFAAs. The adverse effects of other PFAS, including PFAA precursors (pre-PFAAs), are much less well studied, as confirmed in the present assessment. Despite careful selection of substances that should have been the most data rich, there were generally insufficient REACH registration and CompTox® data to definitively conclude on hazards for the other PFAS groups assessed. However, indications of hazard for some endpoints were evident across all the groups considered. The informal environmental assessments performed by the Environment Agency were more in-depth and provided additional lines of evidence; they were able to conclude on hazard for the specific substances considered to the extent that information was available, but noting that in several cases that information was limited. The non-UK assessments have generally focused on, and demonstrated hazard (according to the respective country's opinions) for, the long-chain and short-chain PFCAs and PFSAs and their precursors.

Considering these lines of evidence, this high-level hazard assessment has demonstrated that, despite their widespread use, a reliable understanding of hazard for many PFAS is not yet possible (individually or at group level), beyond the accepted view that they are in general very persistent.

However, Section 3 and Annex VII detail that many substances within the prioritised PFAS groups are precursors to substances in key arrowhead groups (long-chain and

short-chain PFCAs, PFSAs and PFPAs; i.e., the PFAAs). Direct exposure to pre-PFAAs may cause adverse effects in humans by (i) transformation to toxic PFAAs *in vivo*, (ii) toxic effects caused by pre-PFAAs themselves, or (iii) toxic effects induced by intermediate transformation products (McDonough *et al.*, 2022). Likewise, transformation of pre-PFAAs in the environment can lead to environmental and consequently secondary human exposure to PFAAs. Of the groups prioritised for hazard assessment, the following potentially have PFAAs as their final transformation products:

- Perfluoroalkenes (final degradation products are PFCAs)
- Perfluoroalkyl epoxides and vinyl ethers (i.e., excluding PFEs) (final degradation products are the PFCAs)
- Side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives (final degradation products are the respective PFCAs and PFSAs)
- PFPiAs (possible degradation to PFCAs and/or perfluoroalkyl phosphonic acids (PFPAs), although limited or no specific information available).

Currently, a common approach to hazard assessment of PFAS, which has, for example, been adopted by the EU, is for assessments to encompass both precursors and transformation products; therefore, if an arrowhead (group) is concluded to be PBT/vPvB, then automatically any precursor (group) to the arrowhead (group) should also be considered PBT/vPvB.

The approach of concluding hazard on a precursor (group) based on its arrowhead (group) assumes that the arrowheads will be the substances that drive the concern (e.g., with PBT properties) (Cousins *et al.*, 2020a). However, Cousins *et al.* (2020a) noted that some precursor PFAS or intermediate degradation products might be more hazardous than the arrowhead degradation products. For example, 6:2 fluorotelomer alcohol (6:2 FTOH) is reported to be more toxic to rodents than its degradation product PFHxA (Rice *et al.*, 2020). McDonough *et al.* (2022) reported other examples of precursor substances being more toxic than their terminal degradation products. This therefore reflects a potential uncertainty in the arrowhead approach to PFAS grouping.

In using the arrowhead groups (in this assessment, the long-chain and short-chain PFCAs and PFSAs) to drive the concern, it should also be noted that, except for the long-chain PFCAs group, which has been identified as PBT under the Stockholm Convention (UN POPs, 2022b, 2022c) and by ECHA (European Commission, 2021), no PFAS group has been unequivocally concluded as hazardous in any national or international assessment. Again, this is partly due to an absence of data critical to definitive conclusion.

However, considering the short-chain PFSAAs, PFBS has been identified by the EU as having high persistence, high mobility, high potential for long-range transport, moderate bioaccumulation and to be toxic<sup>6</sup>; and PFOS has been identified as POP under the Stockholm Convention. It should therefore be possible to infer that all chain lengths in between PFBS and PFOS, which encompass the short-chain PFSAAs, may be problematic.

Considering the short-chain PFCAs, many of these substances may have a hazard associated with PMT/vPvM type concerns. This hazard assessment notes that TFA is a substance of concern, since there are indications that it might cause developmental toxicity. In addition, in the EU proposal to restrict PFHxA, one of the lines of evidence presented was enrichment in plants (Brendel *et al.*, 2018), which may be a potential route for entering the human food chain (see Section 3) and a potential for developmental toxicity was also highlighted. Thus, in line with the short-chain PFSAAs, it could be inferred that all chain lengths in between TFA and PFHxA, which encompass the short-chain PFCAs, might be problematic. In relation to TFA, it is noted that some of the substances in the HFCs, HFEs and HFOs group (i.e., a commercially significant, high tonnage group in the UK) are F-gases that could potentially transform to TFA under the correct conditions.

For some of the prioritised groups, however, there is little evidence for further degradation in the environment (see Section 3). These were:

- PFECA and precursors
- Perfluoroalkanes and perfluorocycloalkanes
- PFESA and precursors
- PFEs (excluding the vinyl ethers and epoxides)
- PFPAs (excluding the PFPiAs)

The groups assessed can therefore be summarised as follows in terms of their degradation into arrowheads:

### **PFAAs**

As noted in this section, the hazards of the PFCAs and PFSAAs arrowheads have been well characterised and form the basis of the arrowhead approach to PFAS grouping.

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<sup>6</sup> The UK at the EU Member State Committee (MSC) highlighted a lack of reliable data to address certain endpoints and weaknesses in the lines of evidence presented in identifying PFBS as an SVHC; nevertheless, the hazards associated with PFBS do require further consideration.

## Groups that transform to PFAAs

No hazard information for the side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives group was identified. In line with the arrowhead approach to PFAS grouping, the hazards of this group can be inferred from the final degradation products. The same can be assumed for the perfluoroalkene group.

No hazard data for the PFPA and PFPiA group was identified. PFPiA substances are predicted to transform to PFPAs and ultimately PFCAs arrowheads (Wang *et al.*, 2016). There are limited data with regards to transformation pathways. From a physicochemical perspective they have been observed to behave in a similar way to PFSAs, but are less mobile than their analogous PFSAs in soils (Lee and Mabury, 2017). They have also been noted to have some similarities in their modes of action to long-chain PFAAs; their presence simultaneously with other PFAAs could lead to an additive effect (Wang *et al.*, 2016).

## F-gases

REACH registration information, a non-UK assessment and informal environmental assessments for several substances in the group 'polyfluoroalkyl substances: HFCs, HFEs and HFOs' did not highlight a hazard concern of relevance to this RMOA for human health. However, substances in this group can transform to TFA (itself a member of the short-chain PFCAs group), for which a potential concern for developmental toxicity has been identified. Some of the substances screened as P/vP or vM.

## Groups for which there is little or no evidence of further degradation

Informal environmental assessments for some individual members of these groups have been undertaken. Whilst some of these substances screened as P/vP, B/vB, M/vM or T, in general there was insufficient information to reach a firm conclusion on PBT, PMT, vP/vB or vP/vM status and/or human-health effects.

## 4.5 Summary of hazards

The focus of the hazard assessment was primarily to determine if conclusions could be reached on the PBT, PMT and vP/vB or vP/vM status of substances in the assessed groups. In terms of human-health effects, those arrowhead substances with mandatory classifications listed in Table 4.2.1 meet the T criteria in UK REACH Annex 13 Section 1.3.3. The listed substances are in the long-chain PFCAs and long-chain PFSA groups; these are groups that have been identified as PBT at a group level or contain substances that are PBT or vP/vB. Some of the short-chain PFCAs potentially meet the T criterion for human-health effects, although a more in-depth assessment of the available data would be required, for example for TFA. Some jurisdictions have proposed or identified substances in the short-chain PFCA group as PBT, vP/vB or having various combinations of persistence, mobility, long-range transport potential and toxicity.

The human-health information on substances in the short-chain PFSA group was contradictory: whilst one substance had a mandatory classification that met the T criterion, none of the REACH registration information for the other substances indicated concerns for relevant hazards. One substance in this group has been identified as persistent and mobile by one jurisdiction, but another concluded that the arrowhead anions of C<sub>5</sub>-C<sub>7</sub> PFSA were persistent but there was insufficient information to say if they were bioaccumulative or toxic.

A small number of individual substances in other assessed groups would meet or gave indications that they might meet the T criterion for human-health effects. For the other substances, the T criterion would not be met or the information was limited. Whilst all these substances screened as P or vP, there was no consistency in their screening for mobility, bioaccumulation or toxicity. No hazard information was identified for three groups.

Application of the arrowhead approach to grouping PFAS and drawing conclusions on hazards that encompass both precursor substances and their final degradation products (PFAAs) is currently a common way of assessing the large number of substances that fall within the various definitions of PFAS (Cousins *et al.* (2020a)). The presumption is that the PFAAs will be the substances in the groups with the greatest concern; they are also the ones for which the most hazard information is available. There is a degree of uncertainty in this approach, in that some precursors appear to be more toxic than their final degradation products. However, given the large number of precursor substances for which there is little or no hazard information, the arrowhead approach provides a pragmatic solution. The same approach could be applied to those groups that transform to TFA in particular.

Not all PFAS groups will degrade in the environment to arrowhead PFAAs. Some substances in these groups have been identified as being manufactured in the UK or detected in the UK environment. Although preliminary conclusions on the hazards of these substances have been made, the information available is somewhat limited and does not allow definitive conclusions to be made.



## 5 OVERVIEW OF OTHER PROCESSES/LEGISLATION

### 5.1 Domestic regulation and control

The following text captures the existing regulatory controls which apply to PFAS in scope of this RMOA (see Section 1 for substance identity).

#### 5.1.1 Worker protection

#### **The Control of Substances Hazardous to Health Regulations 2002 (COSHH)**<sup>7</sup>

This legislation applies in Great Britain (GB).

In GB, risks to human health arising from the use of chemicals are managed by the Control of Substances Hazardous to Health (COSHH) regulations. The COSHH regulations outline an employer's responsibilities in GB to protect the health and safety of people exposed to the occupational use of substances hazardous to health.

Dutyholders are required to prevent, or, where this is not reasonably practicable, control exposure to hazardous substances to protect the health of people affected by their work activities.

Under COSHH, for substances that are classified as Carcinogens or Mutagens, Regulation 7(7) imposes a duty on employers to reduce exposure to a level as low as reasonably practicable (ALARP). As noted in section 4, most PFAS that have a MCL are carcinogenic meaning that exposure to those substance will need to be kept to ALARP. COSHH can also impose a Workplace Exposure Limit (WEL). There are no current WELs for any PFAS due to the uncertainty with regard to human health hazard profiles of the various groups as well as the use in the workplace. Those that are classified as carcinogenic are subject to ALARP.

COSHH is also supported by other health and safety legislation such as the Management of Health and Safety at Work Regulations, and even more broadly the Health and Safety at Work Act. This legislation also requires that dutyholders take responsibility for assessing and controlling the hazards created by their work.

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<sup>7</sup> <https://www.hse.gov.uk/pubns/books/l5.htm> (accessed April 2022). The Control of Substances Hazardous to Health Regulations 2002 implemented the EU-wide Chemical Agents Directive (CAD), Biological Agents Directive (BAD) and Carcinogen and Mutagens Directive (CMD) in GB. Further information about the provisions of these regulations is available at: <https://www.hse.gov.uk/coshh/> (accessed April 2022).

### 5.1.2 Legislation aimed at protection of the general public

#### **General Product Safety Regulations 2005 (GPSR)<sup>8</sup>**

The GPSR impose requirements concerning the safety of products intended for consumers or which are likely to be used by consumers. The regulations contain a general requirement that producers are obliged to place only safe products on the market.

In this context, a safe product is something that under normal or reasonably foreseeable conditions of use does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons. Categories of consumers at risk when using the product, in particular children and the elderly are to be taken into account when considering acceptability.

The broad definition of “product” means that PFAS-containing mixtures and articles that are available for use by consumers (even if not explicitly intended as consumer products) fall within the scope of these regulations. Regulation 6 of this statutory instrument states that when a product conforms to a voluntary national standard of the United Kingdom, as determined and published by the Secretary of State, the product shall be presumed to be a safe product so far as concerns the risks and categories of risk covered by the standard. In the absence of other legislation or standards, demonstration of safe use in the context of a REACH registration may be taken as evidence that a product can be regarded as safe under the GPSR. Additionally, where hazard data is known and a substance has an MCL this would deem that the product is not a safe product in line with this legislation.

### 5.1.3 Risk management of drinking water quality

#### **GB risk management of drinking water supplies**

In the UK, regulation of drinking water is devolved. In England and Wales, the quality of public drinking water is regulated by the Water Supply (Water Quality) Regulations 2016<sup>9</sup> (as amended) in England, and the Water Supply (Water Quality) Regulations 2018<sup>10</sup> in Wales respectively. The requirements of these Regulations are enforced

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<sup>8</sup> <https://www.legislation.gov.uk/ukxi/2005/1803/contents/made> (accessed November 2022). The General Product Safety Regulations implement directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. At the time that the regulations were reviewed for this RMOA, updates to the legal text were pending. Further information about the provisions of these regulations is available at: <https://www.gov.uk/government/publications/general-product-safety-regulations-2005/general-product-safety-regulations-2005-great-britain> (accessed April 2022).

<sup>9</sup> <https://www.legislation.gov.uk/ukxi/2016/614/contents> (accessed November 2022). The Water Supply (Water Quality) Regulations 2016 implement directive 98/83/EC of the European Parliament and of the Council of 3 1998 on the quality of water intended for human consumption. This legislation is available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0083-20151027> (accessed November 2022).

<sup>10</sup> <https://www.legislation.gov.uk/wsi/2018/647/contents/made> (accessed November 2022).

by the DWI. Private water supplies are regulated by local authorities under the Private Water Supplies (England) Regulations 2016<sup>11</sup> (as amended) and a parallel set of regulations for Wales.

There are no specific standards for PFAS listed in the current Regulations in England and Wales. The Regulations require that, in order to be regarded as “wholesome”, drinking water must not contain any substance at a level which would constitute a potential danger to human health (as well as meeting the other requirements of the Regulations). For compounds where no standard is set, the DWI seeks advice from the UKHSA and, if appropriate, other independent toxicological experts to determine a level at which drinking water does not constitute a potential danger to human health, and therefore could be regarded as wholesome.

In January 2021 the DWI updated their Guidance on the Water Supply (Water Quality) Regulations 2016 specific to PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) concentrations in drinking water.

The guidance sets out requirements for water companies to monitor PFOS and PFOA, and any actions to be taken if concentrations exceed particular thresholds. The DWI subsequently issued an Information Letter in October 2021 that added 45 additional PFAS to the monitoring requirement. The DWI has advised the water industry of a wholesomeness guideline value of 0.1 µg/l for any PFAS, and introduced a tiered system of escalating actions for companies to follow, including monitoring, risk assessment and consultation with health authorities (see section 3.2.1). For sites exceeding the wholesomeness guideline value, companies are required to take remedial action.

The DWI issued updated guidance in March 2022 on monitoring requirements, risk assessment and risk management activities. All companies were required to submit an update of their risk assessment submission to the DWI by 31 August 2022. The risk assessment is now available (DWI, 2022).

In Scotland, the Drinking Water Quality Regulator (DWQR) regulates drinking water quality. The DWQR is responsible for enforcing the standards set out in the Public Water Supplies (Scotland) Regulations 2014<sup>12</sup>. The Public Water Supplies (Scotland) Regulations 2014 was amended in 2022 and now includes a standard of 0.1 µg/l for the sum of 20 named PFAS. DWQR wrote to Scottish Water in 2022 setting out the new requirements for risk assessment and sampling for these PFAS<sup>13</sup>.

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<sup>11</sup> <https://www.legislation.gov.uk/uksi/2016/618/contents/made> (accessed November 2022).

<sup>12</sup> <https://www.legislation.gov.uk/ssi/2014/364/contents/made> (accessed November 2022).

<sup>13</sup> [information-letter-1-2022-risk-assessment-and-sampling-of-poly-and-perfluorinated-alkyl-substances.pdf \(dwqr.scot\)](https://www.dwqr.scot.nhs.uk/information-letter-1-2022-risk-assessment-and-sampling-of-poly-and-perfluorinated-alkyl-substances.pdf) (accessed March 2023)

#### 5.1.4 Risk management of food quality

##### **GB risk management of food quality**

In England and Wales, the presence of chemicals in food and food contact materials is regulated by the Food Standards Agency (FSA). Food Standards Scotland (FSS) has responsibility for food policy in Scotland. The relevant legislation is The Materials and Articles in Contact with Food (England) Regulations 2012, with parallel legislation in Wales and Scotland. Livestock feedstuffs are regulated by the same bodies, but through separate regulations.

There are currently no specific restrictions on PFAS in food or food contact materials.

In September 2020 the European Food Safety Authority (EFSA) issued a scientific Opinion on the risks to people's health from the presence of PFAS in food.

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) has looked at the EFSA opinion and produced a statement (COT 2022). This is not a COT statement on risks from PFAS but a review of the EFSA work and will make up part of an evidence base for next steps in GB.

#### 5.1.5 Environmental protection

##### **Environmental permitting**

Many types of commercial activity that can generate chemical releases to the environment are controlled under environmental permitting regulations that cover England & Wales, and separate regulations that cover Scotland. These regulations transposed the requirements of a number of EU Directives into UK law, and enable the regulation of sites or activities that may be relevant to the management of risks from PFAS. The sites/activities covered include:

- Installations and activities covered by the Industrial Emissions Directive;
- Waste operations and landfill activities;
- Handling of end-of-life motor vehicles;
- Handling of waste electrical and electronic equipment;
- Waste incineration plants;
- Water discharge activities; and
- Groundwater activities.

Different regulatory measures may apply, depending upon the type of activity or site and the scale of environmental risk involved. Several GB sites that manufacture or

use PFAS hold environmental permits, but there are currently no permit conditions that specifically target PFAS for control.

### **River Basin Management Planning**

Water protection legislation is implemented in the UK by a series of related regulations (such as Water Environment and Water Services (Scotland) Act 2003)<sup>14</sup> and The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017)<sup>15</sup>. The overall aims include the achievement of good chemical status for all surface water bodies (rivers, lakes, estuaries and coastal waters) by 2027. Chemical status in surface waters depends on compliance with Environmental Quality Standards (EQS) for priority substances (including priority hazardous substances, for which the aim is the elimination of emissions).

To date only PFOS has been classed as a priority hazardous substance in surface waters (since 2015). For inland surface waters, the water column based Annual Average (AA) EQS is 0.65 ng/L. A biota EQS of 9.1 µg/kg wet weight (fish) has also been set to protect people who eat fish, as well as predatory wildlife.

The Water Environment (Water Framework Directive) England and Wales Regulations 2017 also require 'good' chemical status in groundwater bodies by 2027. There are two additional quality objectives that apply to all groundwater: to prevent or limit the inputs of pollutants into groundwater; and implement measures necessary to reverse any significant and sustained upward trend in pollutant concentrations in groundwater. The Water Environment and Water Services (Scotland) Act 2003)<sup>16</sup> requires ensuring the progressive reduction of pollution of groundwater and preventing further pollution of it.

Currently only PFOS is considered as a hazardous substance to groundwater (UKTAG, 2019). The Joint Agencies Groundwater Directive Advisory Group (JAGDAG)<sup>17</sup> manages the process for assessing if substances are Hazardous or Non-hazardous to groundwater to implement Schedule 22 of The Environmental Permitting (England and Wales) Regulations 2016<sup>18</sup>. The Groundwater (Water Framework Directive) (England) Direction 2016<sup>19</sup> transposes parts of Directive

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<sup>14</sup> <https://www.legislation.gov.uk/asp/2003/3/part/1/enacted> (Accessed January 2023).

<sup>15</sup> <https://www.legislation.gov.uk/ukxi/2017/407/contents/made> (Accessed November 2022).

<sup>16</sup> <https://www.legislation.gov.uk/asp/2003/3/part/1/enacted> (Accessed January 2023).

<sup>17</sup> <http://www.wfduk.org/stakeholders/jagdag> (Accessed January 2023).

<sup>18</sup> <https://www.legislation.gov.uk/ukxi/2016/1154/schedule/22/made> (Accessed November 2022).

<sup>19</sup> <https://www.gov.uk/government/publications/the-groundwater-water-framework-directive-england-direction-2016> (Accessed November 2022).

2006/118/EC<sup>20</sup> that relate to classification and groundwater standards and thresholds. There are no PFAS groundwater quality standards in this direction currently.

Deterioration of surface water bodies, groundwater bodies and their ecosystems must also be prevented under the water protection legislation.

### 5.1.6 Risk management under UK REACH

UK REACH is a regulation that applies to chemical substances that are manufactured in or imported into GB. UK REACH applies to all individual chemical substances on their own, in mixtures or in articles. Manufacturers and importers of substances are required to understand the hazards of the substances they are supplying to the GB market.

UK REACH Registrants must demonstrate that their substances can be used safely. This entails a risk assessment for PFAS that are identified as hazardous and supplied above 10 tonnes/year. However, registrants who are able to take advantage of the transitional arrangement under UK REACH do not have to submit full registration data until the relevant deadline. An extension to the current registration deadlines has been consulted on in 2022 and legislation to extend these deadlines by 3 years will be brought forward.<sup>21</sup>

Thirty-six PFAS had UK REACH registrations as of July 2022. This would be expected to represent the majority of the tonnage of PFAS manufactured in GB, but is probably only a small proportion of the total number of PFAS in commercial use in GB. PFAS imports (>1 tonne/year) from EU suppliers for which the UK importer had no previous registration obligation under EU REACH are covered by DUINs up until full UK registrations are required. The number of PFAS that will actually be registered in due course is unknown.

Registrants must demonstrate that their substances can be used safely. This entails a risk assessment for PFAS that are identified as hazardous and supplied above 10 tonnes/year. However, many registered PFAS are supplied at low volumes and not identified as hazardous, so registration by itself cannot minimise releases for all PFAS. There is no current obligation for registrants to assess endocrine disrupting properties or PMT/vPvM properties of either the substance or any arrowhead transformation product. In addition, the grandfathering arrangements mean that many UK-registered PFAS lack a full description of exposure and risk, and this may not be addressed until the full registration deadline.

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<sup>20</sup> <https://www.legislation.gov.uk/eudr/2006/118/contents#> (Accessed November 2022) Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration.

<sup>21</sup> <https://www.gov.uk/government/consultations/uk-reach-extending-submission-deadlines-for-transitional-registrations> (Accessed January 2023).

There are likely to be significant imports of PFAS in articles, including in textiles, upholstery, leather, apparel and electronic equipment. It is not possible to manage unintentional releases from imported articles through the registration process, as registration is not required.

### **Identification as a Substance of Very High Concern and Authorisation**

Under REACH, substances can be identified as substances of very high concern (SVHCs) if they meet one or more of the hazard criteria outlined in Article 57. When a substance is identified as an SVHC, it is added to the Candidate List. This is a list of substances which may be considered for inclusion in Annex 14 of UK REACH (the Authorisation List).

Adding a substance to the UK Candidate List introduces new responsibilities for actors in the supply chain including duties to communicate information to customers about the SVHC in articles, duties to notify the Agency if you import articles containing the SVHC, and duties to provide safety data sheets to customers receiving the substance or a mixture containing the substance. Typically these duties are triggered where the concentration of an SVHC in a mixture or article is 0.1% or more, though this may not always be the case

There are no PFAS on the UK REACH Authorisation List (Annex 14), but the following are identified as SVHCs on the UK REACH Candidate List:

- Perfluorooctanoic acid (PFOA) and its ammonium salt – persistent, bioaccumulative and toxic (PBT), reprotoxic;
- C<sub>9</sub>-C<sub>10</sub> PFCAs and their ammonium and sodium salts – PBT, reprotoxic;
- C<sub>11</sub>-C<sub>14</sub> PFCAs – very persistent, very bioaccumulative (vPvB);
- PFHxS and its salts – vPvB;
- 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (HFPO-DA) (the ammonium salt is commonly known as GenX®); and
- perfluorobutane sulfonic acid (PFBS) and its salts<sup>22</sup>.

Candidate Listing compels the Registrant(s) of an SVHC to identify the substance as such to downstream users and provides a flag to users about its undesirable properties. Under UK REACH, producers and importers of articles have a legal obligation to notify the Agency if any SVHC included in the Candidate List is present in their articles above the threshold of 0.1% by weight and if the quantity of the SVHC in those articles is over 1 tonne per producer/importer per year.

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<sup>22</sup> HFPO-DA and PFBS were identified as being of equivalent concern to carcinogens, mutagens and reprotoxicants (CMRs) and PBT/vPvB chemicals, based on their persistence, mobility and toxicity. This combination of properties was considered to pose a threat to human health and wildlife when exposed through the environment (including through drinking water).

## **Restrictions**

Restrictions can be introduced when there is an unacceptable risk to human health or the environment arising from the manufacture, placing on the market and use of a substance, and where the risk needs to be addressed across the whole marketplace.

There are currently two UK REACH restrictions of PFAS in force within GB.

PFOA and its salts were restricted due to its PBT properties, the detail of the restriction can be found in entry 68 of Annex 17 to UK REACH. This includes the exemptions from restrictions for medical devices, photographic applications and also for fire-fighting foams that were already in use before July 2020 or are used in the manufacture of other fire-fighting foam mixtures etc.

PFOA is also a Persistent Organic Pollutant (POPs) under the United Nations Stockholm Convention (see Section 5.1.7). The UK REACH restriction is expected to be revoked in due course as it will be superseded by the UK POPs regulations, which prohibits the manufacture, placing on the market and/or use of PFOA (with the exception of some specific and time-limited exemptions).

The second UK REACH restriction is for the perfluorinated silane (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in sprays used for the general public. The basis for the restriction is respiratory sensitisation.

### **5.1.7 Risk management under Persistent Organic Pollutants (POPs) legislation**

The POPs Regulation implements the global UN Stockholm Convention on POPs, restricting the production, placing on the market and use of substances classed as POPs. Specific time-limited use exemptions are permitted. Listing in Annex A (elimination) or Annex B (restriction) of the Stockholm Convention can be implemented with a threshold concentration to allow recycling of contaminated materials where this represents the best environmental option.

To be considered for listing as a POP, a substance must meet the Annex D screening criteria: it must be persistent, significantly bioaccumulative, have adverse effects on human health and the environment, and have the potential for long-range transport.

The UN Stockholm Convention on Persistent Organic Pollutants (POPs) is implemented in GB by the retained EU Regulation 2019/1021<sup>23</sup>, as amended by The

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<sup>23</sup> <https://www.legislation.gov.uk/eur/2019/1021/introduction> (Accessed November 2022).



Persistent Organic Pollutants (Amendment) (EU Exit) Regulations 2020<sup>24</sup>. These regulations restrict both PFOS and PFOA.

- PFOS, its salts and perfluorooctanesulfanylfluoride (PFOSF) were listed as POPs in Annex B (restriction) in 2009. There are very limited circumstances under which this group may currently be produced and used:
- Specific exemptions apply to use for hard-metal plating in closed-loop systems and fire-fighting foam for Class B fires in installed systems, including both mobile and fixed systems.
- Insect baits containing sulfluramid (CAS no. 4151-50-2) are identified an acceptable use for control of leaf-cutting ants (*Atta* spp. and *Acromyrmex* spp.) for agricultural use only.

These are due to be reviewed in 2023.

PFOA, its salts and PFOA-related compounds were listed in Annex A (elimination) in 2019. Production of new fire-fighting foams containing PFOA is expressly prohibited, but there are a number of exempt uses:

- Photolithography or etch processes in semiconductor manufacturing
- Photographic coatings applied to films
- Textiles for oil and water repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety
- Invasive and implantable medical devices
- Fire-fighting foam for Class B fires in installed systems, including both mobile and fixed systems
- Use of perfluorooctyl iodide for the production of perfluorooctyl bromide for the purpose of producing pharmaceutical products
- Manufacture of PTFE and polyvinylidene fluoride (PVDF) for the production of:
- High-performance, corrosion-resistant gas filter membranes, water filter membranes and membranes for medical textiles
- Industrial waste heat exchanger equipment
- Industrial sealants capable of preventing leakage of volatile organic compounds and PM2.5 particulates
- Manufacture of polyfluoroethylene propylene (FEP) for the production of high-voltage electrical wire and cables for power transmission

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<sup>24</sup> <https://www.legislation.gov.uk/uksi/2020/1358/contents/made> (Accessed November 2022).

- **Manufacture of fluoroelastomers for the production of O-rings, v-belts and plastic accessories for car interiors**

Two further substance groups are currently progressing through the POPs decision making process:

- The Conference of the Parties agreed to list PFHxS, its salts and PFHxS-related compounds to Annex A of the Stockholm Convention without specific exemptions at COP-10 in June 2022.
- A proposal to list C9-C21 PFCAs as POPs was submitted by Canada in 2021. At POP Review Committee (POPRC) 18 in September 2022, the meeting agreed that the proposed group of substances met the Annex E criteria of the Convention (the hazard criteria for listing). A Risk Management Evaluation will now be performed, with a recommendation for listing expected to be put to the COP in 2025.

#### 5.1.8 Other relevant GB regulation

##### **GB regulation of F-gases**

F-gases are highly volatile hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), sulphur hexafluoride and other greenhouse gases that contain fluorine. They exert a Global Warming Potential (GWP) higher than carbon dioxide (CO<sub>2</sub>), sometimes many thousands of times higher (on a weight for weight basis). Introduced as replacements for the ozone-depleting chlorofluorocarbons (CFCs), the high GWP F-gases are being phased downwards to meet climate change mitigation targets.

EU Regulation No. 517/2014<sup>25</sup> on fluorinated greenhouse gases has been retained in UK law, and is enforced through The Fluorinated Greenhouse Gases Regulations 2015<sup>26</sup>. It:

- establishes rules on containment, use, recovery and destruction of F-gases, and on related ancillary measures;
- imposes conditions on the placing on the market of specific products and equipment that contain, or whose functioning relies upon, F-gases;
- imposes conditions on specific uses of F-gases; and
- establishes quantitative limits for the placing on the market of HFCs.

Annex I of the Regulation is a non-exhaustive list of specific HFCs, PFCs and sulphur hexafluoride.

<sup>25</sup> <https://www.legislation.gov.uk/eur/2014/517/introduction> (Accessed November 2022).

<sup>26</sup> <https://www.legislation.gov.uk/uksi/2015/310> (Accessed November 2022)

Annex II is a non-exhaustive list of HFCs and HCFCs, fluoroethers, fluoroalcohols and other perfluorinated compounds, all of which are covered by reporting requirements.

HFCs are also subject to a global phase-down under the Montreal Protocol Kigali Amendment, through which the UK has committed to an end target of 85% cut in HFC consumption by 2036 (from a 2011-2013 average baseline).

The Mobile Air Conditioning (MAC) Directive 2006/40/EC<sup>27</sup>, implemented in the UK by The Motor Vehicles (Type Approval for Goods Vehicles) (Great Britain) (Amendment) Regulations 2009<sup>28</sup>, prohibits the use of F-gases with a global warming potential of more than 150 times greater than CO<sub>2</sub> in new types of cars and vans introduced from 2011, and in all new cars and vans produced from 2017.

The UK aims to achieve a 79% phase down of HFCs by 2030, from the average use between 2015 and 2019. This reduction is to be realised by:

- Gradual phase-down of the quantities of HFCs used by means of quota. The phase-down only applies to HFCs and not to PFCs (or sulphur hexafluoride).
- Prohibitions on use and placement on the market, insofar as technically feasible and more climate friendly alternatives are available.
- Continuation and expansion of the scope of regulations concerning leak tests, certification, disposal and labelling.

The UK is currently on track to achieve the phase down target, as set out in *Annex V of EU Regulation No. 517/2014*<sup>29</sup> as retained in UK law as it applies in Great Britain. The phasedown is implemented through gradual reduction of quotas issued to businesses by the Environment Agency.

The following UK REACH-registered PFAS fall within the scope of Annex I of the F-gas regulations, with HFCs being subject to phasedown:

**Table 5.1.1: UK REACH registered PFAS falling within Annex I of the F-Gas regulations**

Industrial ID	Chemical name	Chemical formula	PFAS Group
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<sup>27</sup> <https://www.legislation.gov.uk/eudr/2006/40/2006-05-17#> (Accessed November 2022).

<sup>28</sup> <https://www.legislation.gov.uk/uksi/2009/2084/made> (Accessed November 2022).

<sup>29</sup> <https://www.legislation.gov.uk/eur/2014/517/annex/V> (Accessed November 2022).

HFC-125	Pentafluoroethane	CHF <sub>2</sub> CF <sub>3</sub>	Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)
HFC-227ea	1,1,1,2,3,3,3-Heptafluoropropane	CF <sub>3</sub> CHFCF <sub>3</sub>	Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)
PFC-14	Tetrafluoromethane (perfluoromethane, carbon tetrafluoride)	CF <sub>4</sub>	Perfluoroalkanes and perfluorocycloalkanes
PFC-116	Hexafluoroethane (perfluoroethane)	C <sub>2</sub> F <sub>6</sub>	Perfluoroalkanes and perfluorocycloalkanes
PFC-218	Octafluoropropane (perfluoropropane)	C <sub>3</sub> F <sub>8</sub>	Perfluoroalkanes and perfluorocycloalkanes

The following UK REACH-registered PFAS fall within the scope of Annex II of the F-gas regulations, being subject to monitoring and reporting:

**Table 5.1.2 UK REACH registered PFAS falling within Annex II of the F-Gas regulations**

Industrial ID	Chemical name	Chemical formula	PFAS Group
HFE-347pcf2	1,1,1,2-Tetrafluoro-1-(2,2,2-trifluoroethoxy)-ethane	CHF <sub>2</sub> CF <sub>2</sub> OCH <sub>2</sub> CF <sub>3</sub>	Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)

Six PFAS that have DUINs in UK REACH also fall within the scope of Annex I of the F-gas regulations:

**Table 5.1.3 UK REACH DUINs for PFAS falling within Annex I of the F-Gas regulations**

Industrial ID	Chemical name	Chemical formula	PFAS Group
HFC-125	1,1,1,3,3-Pentafluorobutane	C <sub>4</sub> H <sub>5</sub> F <sub>5</sub>	Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)
HFC-245fa1	1,1,1,3,3-Pentafluoropropane	C <sub>3</sub> H <sub>3</sub> F <sub>5</sub>	
HFC-356pcf2	1,1,1,3,3,3-Hexafluoropropane	C <sub>3</sub> H <sub>2</sub> F <sub>6</sub>	
HFC-236fa	1,1,1,2,3,3,3-Heptafluoropropane	C <sub>3</sub> HF <sub>7</sub>	
PFC-31-10	Norflurane	C <sub>2</sub> H <sub>2</sub> F <sub>4</sub>	
HFC-143a	1,1,1,2,2,3,4,5,5,5-Decafluoropentane	C <sub>5</sub> H <sub>2</sub> F <sub>10</sub>	

**The Detergents Regulation - Regulation (EC) No 648/2004 on Detergents (as amended)**<sup>30</sup>

The Detergents Regulations and its [associated amending regulations](#) establishes technical standards and requirements in relation to the biodegradability of surfactants in detergents. Surfactants and detergents containing surfactants which meet the criteria outlined in Annex III of this regulation may be placed on the market without further limitations relating to biodegradability. Where surfactants do not meet these criteria, detergent manufacturers must apply for a derogation or choose an alternative surfactant.

Some PFAS substances are surfactants (such as the fluorotelomers) so those placing these substances on the market must comply with the Detergent Regulations – there are no specific bans or limitations on PFAS but they must comply with respect to how products should be labelled in order to protect human health (to avoid allergic reactions).

<sup>30</sup> <https://www.legislation.gov.uk/ukxi/2010/740/contents> (accessed April 2022). The Detergents Regulation is retained EU legislation. At the time that the regulations were reviewed for this RMOA, updates to the legal text were pending. Further information about the provisions of this regulation is available here: <https://www.hse.gov.uk/detergents/> (accessed April 2022).

## GB regulation of pesticides

Pesticides, also known as 'plant protection products' (PPP) are used to control pests, weeds and diseases and are defined and regulated under Regulation (EC) No 1107/2009<sup>31</sup>, which has been retained by GB. Examples of PPP include insecticides, fungicides, herbicides, molluscicides, and plant growth regulators. They can exist in many forms, such as solid granules, powders or liquids and consist of one or more active substances co-formulated with other materials. The active substance or substances within a pesticide has the controlling effect on the pest, weed or disease.

PFAS may be present in PPP. All businesses and organisations in the PPP supply and use chain must comply with the Official Controls (Plant Protection Products) Regulations 2020<sup>32</sup>. This includes registering with the Competent Authority. This is Defra in England and the Scottish and Welsh Governments in Scotland and Wales, respectively. Defra will collect this information on behalf of Scottish and Welsh Governments.

Before any pesticide product can be used, sold, supplied or stored the active substances contained within must be authorised for use. An active substance must be approved before it can be included in any pesticide product authorised for use in GB. The approvals register<sup>33</sup> lists the approved active substances for GB. The pesticides register database<sup>34</sup> lists the pesticide products authorised for use in GB and Northern Ireland which have been approved after their active substances have been authorised for use in GB.

If an adjuvant for use with a pesticide in the UK is marketed, there must be an application for its inclusion on the Official List of Adjuvants<sup>35</sup>. The list gives details of the adjuvant products that may be used with pesticides and the conditions of use that they are subject to.

A maximum residue level (MRL) is the maximum concentration of a pesticide residue in or on food or feed that is legally tolerated when a pesticide is applied correctly.

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<sup>31</sup> [Regulation \(EC\) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC \(legislation.gov.uk\) \(accessed January 2023\).](#)

<sup>32</sup> [The Official Controls \(Plant Protection Products\) Regulations 2020 \(legislation.gov.uk\)](#) (accessed January 2023). From 1 Jan 2021 the relevant EU law in relation to the regulation of plant protection products was retained in GB law and kept the same official titles, for example, Regulation (EC) 1107/2009. Northern Ireland is still subject to existing EU law.

<sup>33</sup> [GB Pesticides Approvals Register - HSE](#) (accessed January 2023).

<sup>34</sup> [Pesticides Register of Authorised Plant Protection Products](#) (accessed January 2023).

<sup>35</sup> <https://secure.pesticides.gov.uk/adjuvants/Search.aspx> (accessed January 2023). An adjuvant is a substance other than water that does not have significant pesticidal properties but which enhances or is intended to enhance the effectiveness of a pesticide product.

MRLs apply to produce both treated and imported into GB. An import tolerance is a specific MRL set on imported food or feed.

### **GB regulation of pharmaceuticals**

The Human Medicines Regulations (as amended) regulate medical products in GB – these regulations require those who manufacture, import or distribute medicinal products to have licence. Those who have a licence must comply with certain conditions set out by the Medicines and Healthcare Products Regulatory Authority (MHRA) and must have scientifically evaluated the product that they are marketing to ensure that they minimise and prevent risks, taking appropriate measures to minimise these if found. These licences can be revoked if it is found that any product is harmful. Harmful effects can be reported to the MHRA via the pharmacovigilance system.

## **5.2 Overview of relevant international regulatory activities/assessments**

### **5.2.1 European Union**

#### **Risk management under EU REACH**

##### Additional EU REACH SVHCs

At the time of this RMOA, a formal proposal to identify the reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl) morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl) morpholine as a PBT substance is the subject of a current assessment by ECHA.

The ECHA Registry of Intentions indicates that a dossier is being prepared to identify perfluoroheptanoic acid (PFHpA) as a PBT/vPvB substance.

##### Additional EU restrictions

The EU has been working on several EU REACH restrictions of PFAS since the UK exited, and these are briefly summarised below.

A restriction of C<sub>9</sub>-C<sub>14</sub> PFCAs, their salts and precursors came into force on 25 August 2021. Companies cannot use them or place them on the market in a mixture, article or as constituent in another substance above specific concentration limits from 25 February 2023. The scope extends to substances that can be expected to transform to C<sub>9</sub>-C<sub>14</sub> PFCAs in the environment. The aim is to reduce risks due to their PBT or vPvB properties by minimising emissions. Various derogations are included for specific applications with differing deadlines. These concern: use as a transported isolated intermediate, textiles used to protect workers from dangerous liquids, fluoropolymer manufacture for corrosion resistant membranes, industrial heat exchanger equipment and sealants, semiconductor manufacturing, photographic coatings, some types of medical device, fire-fighting

foam (subject to conditions), and PTFE micro powders produced by ionising irradiation or by thermal degradation.

These are not commercially important substances, but were significant constituents of PFOA. The purpose of the restriction was therefore to avoid regrettable substitution of PFOA. The expected listing of long-chain PFCAs as POPs is expected to eventually result in its revocation.

A proposal to restrict the manufacture, use and placing on the market of perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances is currently with the European Commission for decision making. The aim is to reduce risks due to the vPvB properties of PFHxS by minimising emissions.

Historically, PFHxS was found in water and stain-resistant coatings in imported articles, particularly carpets, leather goods and apparel, but it is not registered under EU REACH. The motivation behind the restriction was to prevent substitution of PFOA by PFHxS in fire-fighting foams and to minimise emissions from imported articles or mixtures.

Like the long-chain PFCAs restriction, further risk management of PFHxS as a POP is expected to eventually result in the revocation of the restriction, if adopted.

A proposal to restrict the manufacture, use and placing on the market of perfluorohexanoic acid (PFHxA), its salts and related substances is currently with the European Commission for decision making. The aim is to reduce risks due to PFHxAs extreme persistence, mobility in the aquatic environment, long-range transport potential, potential to enrich in plants, and adverse effects in developmental toxicity studies. The UK did not take any part in the review of this proposal but raised several observations about the claimed hazardous properties during an earlier consultation to identify PFHxA as an SVHC (which was subsequently withdrawn).

These substances are mostly used for the production of fluorinated polymers, either as monomers or as processing aids to control polymerisation. The main polymer use is in textile treatments, with about 55,000 tonnes of precursors such as 6:2 acrylates used annually in the EU. Other precursor surfactants are used as mist suppressants in hard chrome plating, as fire-fighting foam additives, in coatings for paper, and in printer inks.

A proposal to restrict all PFAS in fire-fighting foams used for tackling liquid fuel vapour suppression and liquid fuel fires (Class B fires) was published on 23 March 2022. The 6-month public consultation on the restriction proposal ran until 23 September 2022 and the final ECHA opinion is scheduled to be available during March 2023. The identified risk relates to the same hazards claimed for PFHxA. The aim is to prevent regrettable substitution of PFOA fire-fighting foams and to tackle a significant known source of PFAS pollution (an estimated 18,000 tonnes of PFAS-containing foam is sold in the EU each year).



Five EU Member States – the Netherlands, Germany, Sweden, Denmark and Norway – are developing a broad restriction proposal for all PFAS in scope of the OECD definition. The expected date of dossier submission was initially July 2022 but is now January 2023. It is expected that the restriction dossier will be justified on a similar basis to the approaches used for PFHxA and fire-fighting.

### **River basin planning in the EU – Water Framework Directive and Groundwater Directive**

There are moves within the EU to consider further PFAS under this legislation. The EU has draft new proposals (October 2022) to amend the Water Framework Directive and Groundwater Directive (European Commission, 2022a, 2022b), to expand the list of Priority Substances to include 24 PFAS under a Sum of PFAS with Relative Potency Factors compared to PFOA.

Specific PFAS identified as SVHCs (e.g., PBT, vPvB, substances of equivalent level of concern) and key PFAS often found in the environment could consequently be identified as priority hazardous substances.

### **EU risk management of drinking water supplies**

Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), which took effect on 12 January 2021, includes a limit of 0.5 µg/L for ‘PFAS total’ and a limit of 0.1 µg/L for ‘sum of PFAS’, coming into effect in January 2026.

‘Sum of PFAS’ means the sum of substances considered a concern as regards to water intended for human consumption listed in point 3 of Part B of Annex III; the C<sub>4-13</sub> PFCAs and C<sub>4-13</sub> PFSA. This is a subset of ‘PFAS total’, which is defined as substances that contain a perfluoroalkyl moiety with three or more carbon atoms (i.e. –C<sub>n</sub>F<sub>2n</sub>–, where n ≥ 3) or a perfluoroalkylether moiety with two or more carbon atoms (i.e. –C<sub>n</sub>F<sub>2n</sub>OC<sub>m</sub>F<sub>2m</sub>–, where n and m ≥ 1).

The ‘PFAS total’ value will only apply once technical guidelines for monitoring this parameter are developed in accordance with Article 13(7). Member States may then decide to use either one or both of the parameters.

### **EU risk management of food quality**

Under the EU’s Chemical Strategy (and through related strategies such as the European Green Deal), appropriate risk management of food quality could be achieved through the proposed broad restriction on PFAS.

The EFSA opinion could serve as a basis to set maximum levels for the assessed PFAS substances in food. The Opinion sets a new safety threshold – a group tolerable weekly intake (TWI) of 4.4 nanograms per kilogram of body weight per week – for the main PFAS that accumulate in the human body: PFOA, PFNA, PFOS

and PFHxS. Toddlers and other children are considered to be the most exposed population groups, and exposure during pregnancy and breastfeeding is the main contributor to PFAS levels in infants.

Following this in August 2022, the EC issued [recommendations](#) for the monitoring of PFAS in food. The minimum monitoring suggested covers PFOA, PFNA, PFOS and PFHxS.

### **EU regulation of F-gases**

A [proposed new F-gas Regulation](#) was published on 5 April 2022. It proposes, amongst other things, going even further on the HFC phasedown and new bans. This is in line with a climate law [proposal](#), which requires the European Commission to review, and where necessary revise, all relevant policy instruments to achieve the additional 2030 emission reductions.

#### **5.2.2 United States of America – Federal risk management of PFAS**

The US approach to PFAS sets out an important range of management approaches alongside EU activities. The following sections provide a summary of US activity for reference purposes.

### **PFAS action plan**

The US EPA published a national PFAS Action plan in February 2019, with an updated plan published on 26 February 2020. The primary aims were to:

- Obtain additional toxicity information for PFAS.
- Develop new tools to characterize PFAS in the environment.
- Evaluate clean-up approaches.
- Develop guidance to facilitate clean-up of contaminated groundwater.
- Use enforcement tools to address PFAS exposure in the environment and assist states in enforcement activities.
- Use legal tools such as those in the Toxic Substances Control Act (TSCA) to prevent future PFAS contamination. Note that the US government has not ratified the UN Stockholm Convention on Persistent Organic Pollutants.
- Address PFAS in drinking water using regulatory and other tools.
- Develop new tools and materials to communicate about PFAS.

The plan builds on the following key PFAS management actions that the US EPA announced in 2018.

In October 2021, the US EPA released its [PFAS Strategic Roadmap: EPA's Commitments to Action 2021-24](#), which builds on and accelerates implementation of

policy actions identified in the PFAS Action Plan. The guiding principles underpinning the strategy are:

1. Consider the full lifecycle of PFAS; their properties, uses and exposure pathways.
2. Prevent PFAS from entering the environment in the first place.
3. Hold polluters and other responsible parties accountable.
4. Ensure science-based decision-making.
5. Prioritize protection of disadvantaged communities.

There are three central goals of the roadmap, with associated objectives:

- **Research:** Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science.
- **Restrict:** Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment.
- **Remediate:** Broaden and accelerate the clean-up of PFAS contamination to protect human health and ecological systems.

### **Key actions in effect or under consideration**

#### Ending Low Volume Exemptions for new PFAS

Under the TSCA New Chemicals program, the US EPA reviews risk assessments for new chemicals before they enter the US marketplace. Unreasonable risks must be mitigated before chemical manufacturing can commence. **Previously, some new PFAS were allowed to enter the market through low-volume exemptions (LVEs), but for PFAS there is now a presumption against LVEs.**

#### Reviewing previous decisions on PFAS

The US EPA plans to review past PFAS regulatory decisions, including under the TSCA New Chemicals program, and address those that are now considered insufficiently protective. Companies are being encouraged to voluntarily withdraw PFAS LVEs already granted. As part of this effort, the US EPA could impose additional notice requirements to ensure it can review PFAS before they are used in new ways that might present concerns. In addition, the US EPA plans to issue TSCA Section 5(e) orders for existing PFAS for which significant new use notices have recently been filed with EPA. These would impose rigorous safety requirements as a condition of allowing the significant new use to commence.

#### Phasing out PFAS with inactive uses

For unrestricted PFAS on the TSCA Inventory of Chemicals, the US EPA can designate any currently inactive use as a “significant new use”. This would prevent the use being reactivated until the US EPA had reviewed the potential risks and any safety measures to address unreasonable risks had been put in place.

#### Enhanced PFAS reporting under the Toxics Release Inventory (TRI)

To enhance the quality and quantity of PFAS information collected through TRI, the US EPA intends to categorize the PFAS on the TRI list as “Chemicals of Special Concern” and to remove the *de minimis* eligibility from supplier notification requirements for all “Chemicals of Special Concern.”

#### Finalizing new PFAS reporting under TSCA Section 8

TSCA Section 8(a)(7) provides authority for the US EPA to collect existing information on PFAS. In June 2021, a proposed data-gathering rule was published that would collect certain information on any PFAS manufactured since 2011, including information on uses, production volumes, disposal, exposures, and hazards. The rule would require companies to make a one-time disclosure with no exemptions for by-products, impurities or small businesses.

The US EPA will consider public comments on the proposal and finalize it before January 1, 2023.

#### Regulatory and advisory actions for PFAS in drinking water

Under the Safe Drinking Water Act the US EPA is requiring public water systems to conduct sampling for 29 PFAS in drinking water. The US EPA is developing National Primary Drinking Water Regulations for PFOA and PFOS, and issued [interim health advisories](#) in June 2022. [Final health advisories](#) have also been issued for GenX® chemicals and PFBS.

The Office of Research and Development is also currently developing toxicity assessments for five other PFAS: PFBA, PFHxA, PFHxS, PFNA, and PFDA.

#### Restricting PFAS discharges from industrial sources through an Effluent Limitations Guidelines (ELGs) program

ELGs will set technology-based emission limits for specified pollutants in industrial wastewater discharged into surface waters and into municipal sewage treatment facilities. Based on the results of a multi-industry study, EPA is restricting PFAS discharges from the nine industrial categories in the proposed PFAS Action Act of 2021, as well as other industrial categories such as landfills. This is similar to the BAT approach implemented in GB through environmental permitting (see Section **Error! Reference source not found.**).

## Using the National Pollutant Discharge Elimination System (NPDES) permitting to reduce PFAS discharges to waterways

The US EPA plans to use permitting under the NPDES – equivalent to environmental permitting in GB - to reduce discharges of PFAS at source and obtain more comprehensive information through monitoring the sources of PFAS. The US EPA will use the effluent monitoring data to more effectively target restriction of PFAS in wastewater discharges. NPDES permits may also:

1. Require PFAS elimination/substitution when a reasonable alternative to using PFAS is available in the industrial process;
2. Require best management practices for PFAS-containing fire-fighting foams on stormwater permits;
3. Require enhanced public notification and engagement with downstream communities and public water systems; and
4. Require source control and best management practices to protect wastewater treatment plant discharges and biosolid applications.

Other actions are also underway which can be found on the EPA website

## Federal controls on PFAS-containing fire-fighting foams

Under the 2020 National Defence Authorization Act (NDAA) the US Department of Defence will phase out use of PFAS-containing fire-fighting foam by October 2024 (with an exception for shipboard use). However, the Secretary of Defence may waive the prohibition for one year (renewable once for another year until 2026) if duly justified, such as the protection of life and safety or because no agent or equipment solutions are available that meet the military specifications. The NDAA also immediately prohibits the uncontrolled release of AFFF in testing and training, but allows emergency use or non-emergency use if completely contained (USNDAA, 2020).

## Workplace limits of PFAS in air

The American Conference for Governmental Industrial Hygienists (ACGIH) has established [Threshold Limit Values \(TLVs\)](#) for three PFAS in air: perfluoroisobutylene (PFIB), perfluorobutyl ethylene (a fluorotelomer olefins) and ammonium perfluorooctanoate (APFO, a PFAA and a salt of PFOA). The TLVs (8 hr time-weighted averages and short-term exposure limits - STELs) are:

- Ammonium perfluorooctanoate [CAS 3835-26-1] 8 hour TWA TLV 0.01 mg/m<sup>3</sup>. No STEL.
- Perfluorobutyl ethylene [CAS 19430-93-4] 8 hour TWA TLV 1020 mg/m<sup>3</sup>. No STEL.

- Perfluoroisobutylene [CAS 382-21-8] No 8 hour TWA. TLV set STEL 0.08 mg/m<sup>3</sup> as a ceiling value (so not to be exceeded)

These federal risk management measures for PFAS set a minimum standard, however individual states can legislate to impose more stringent regulation locally.

### 5.2.3 Canada

Canada embarked on an Environmental Performance Agreement with four major manufacturers to phase out PFOA and related compounds from 2010 to 2015 (ECCC, 2018). In 2008, Canada prohibited the use of most PFOS, with select exemptions such as use of existing stocks of PFOS-based fire-fighting foams, and then added PFOS to the Virtual Elimination List in 2009 and to the Prohibition of Certain Toxic Substances Regulations<sup>36</sup> in 2016 (ECCC, 2022). By 2016, Canada had prohibited the import, manufacture, use and sale of PFOS, PFOA, and other long-chain PFCAs (and salts and precursors), with limited exemptions (ECCC, 2022).

In June 2021 Canada submitted a POPs proposal for listing the long-chain C<sub>9</sub>-C<sub>21</sub> PFCAs under the UN Stockholm Convention. The nomination was tabled at POPRC.17 in January 2022 and the draft risk profile considered at POPRC.18 in July 2022.

### 5.2.4 Australia

In Australia, the biggest source of concentrated emissions of PFAS is from historical use of PFAS-containing fire-fighting foams, particularly at fire-fighting training grounds. In 2017, the South Australia state government took steps to develop legislation banning environmentally harmful foams, such as Class B fire-fighting foams containing PFAS (SA EPA, 2018). The Australian Department of Defence has begun phasing out its use of PFOS and PFOA containing fire-fighting foams. Furthermore, PFAS use is also limited by Air Services Australia, a government-owned corporation that provides air traffic control management, and which has transitioned away from fluorinated fire-fighting foam to non-fluorinated fire-fighting foam including the destruction of remaining stockpiles.

The Australian government has developed regulatory, policy and voluntary approaches for responding to PFAS contamination and has published a Position Statement that sets out agreed objectives, including the primary objectives of protecting the environment and minimising human exposure.

The Australian Government also runs an [information portal](#) for PFAS.

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<sup>36</sup> <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2012-285/20210318/P1TT3xt3.html> (accessed November 2022).

The Australian Government published a [PFAS National Environmental Management Plan](#) in January 2018. The plan focusses on three PFAS – PFOS, PFOA and PFHxS – and concentrates on the management of contaminated sites rather than the regulation of active PFAS uses.

The Industrial Chemicals (Notification and Assessment) Act (ICNA Act) required industry to provide toxicity data for new substances (including PFAS) or products containing new PFAS being introduced into Australia. Under the new Australian Industrial Chemicals Introduction Scheme <sup>37</sup> (comparable to REACH), any introduction of a PFAS (4-20 perfluorinated carbons) in excess of 10 kg/year is automatically medium or high risk for human health and the environment. The applicant must apply for an assessment certificate or a commercial evaluation authorisation.

### 5.2.5 Japan

In Japan, there are restrictions on the manufacture, import, export, and use of PFOS and its salts (OECD, 2022e).

Japan has listed PFOS and its salts as a Class I Specified Chemical Substance under the Chemical Substances Control Law (CSCL) and PFOS is subject to export restriction under the country's Foreign Exchange and Foreign Trade Law. The Class I listing occurred in response to the new listing of PFOS under the Stockholm Convention after the government evaluated if PFOS and its salts were persistent, bioaccumulative, and have long-term toxicity for humans and animals.

Additionally, the government of Japan has been conducting environmental monitoring of PFOS since 2009.

### 5.2.6 China

In 2008, the Ministry of Environmental Protection (MEP) issued the first batch of “High Pollution, High Environmental Risk Product Catalogue” which includes high temperature melting membrane fluorine resin coating used on non-stick cookware, kitchenware, and food processing machinery, based on the potential residual PFOA in the products.

Since then, China has implemented; a ban of production, transportation, application, imports and exports of PFOS, its salts and PFOSF, except for specific exemptions and acceptable use; restriction of the production of PFOS and PFOA and support of R&D for alternatives to these substances.

Since 2013, China monitors PFC production and/or emissions, focusing on PFOS and sulphonamide perfluorooctane (FOSA) in water, sediment and fishes in industry parks in Hubei and Zhejiang Provinces. It also focuses on PFOS and PFOA in water,

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<sup>37</sup> <https://www.industrialchemicals.gov.au/> (Accessed November 2022).

sediment and fish, and in an electronic waste dismantling plant in Guangdong Province. The Second Effectiveness Evaluation of the Stockholm Convention in China has started to monitor PFOA and PFOS environmental background levels in air and water of mainland China, Hong Kong (China) and Macau (China).



## 6 CONCLUSIONS AND JUSTIFICATION FOR ACTION:

### 6.1 Concerns about PFAS:

#### 6.1.1 Introduction

PFAS are used extensively not just in GB but globally. They are persistent and have been linked to a range of adverse health effects. Owing to their persistence, “legacy” PFAS, which were used in the past and are now the subject of regulatory action and bans on use, are still present in water, air, soil, humans and animals.

The sheer number of substances within the broad PFAS class makes them a challenge to tackle and group, and there is no globally adopted definition of PFAS for human health or environmental regulation. For this RMOA, the Agency has adopted a working definition that considers the potential for degradation to substances of concern or those that are closely related, i.e. substances for which there is evidence of adverse impact to humans or the environment. Many of these highly persistent substances are referred to as arrowhead substances and encompass those PFAS that represent the most stable transformation product of a precursor PFAS in the environment.

A grouping approach has also been taken in order to help manage the large number of substances in scope and to help to address the risk of regrettable substitution. PFAS have been grouped on the basis of structural similarity, enabling group-level hazard assessment on the assumption that structurally similar substances are likely to pose similar hazards. However, there are drawbacks with this approach in that members of one group may transform into arrowheads that are members of another group and pose different hazards or behave differently in the environment. Also, it is difficult to identify boundaries within groups e.g., considering bioaccumulation potential based on chain length, in the absence of comprehensive data. The PFAS grouping used in this RMOA is set out in Tables 1.2.1 and 1.2.2. This was based on the assessment of existing (published) grouping approaches and refined to represent the PFAS in scope of the definition used in this RMOA and to reflect the PFAS on the GB/EU market. The risks from polymeric PFAS (Table 1.2.2) have been assessed based on UK REACH registered monomers and processing aids.

PFOS was the first PFAS to elicit significant concern. The widespread detection of PFOS and related compounds in human blood, together with their environmental persistence, influenced the main producer of PFOS at that time, 3M, to announce a voluntary halt to production in 2000. Since then, the introduction of replacement PFAS – most notably PFOA – have generated further concerns. Environmental releases of PFOA from a DuPont fluoropolymer manufacturing facility in West Virginia, USA, culminated in a \$671M lawsuit (2017) (known as The C8 Health Project; Frisbee *et al.*, 2009). The transition from C8 chemistry to alternative PFAS has not diminished concerns. In particular, the industry transition to shorter chain PFAS (mainly C6) in products such as fire-fighting foams and surface coatings has

highlighted potential risks from increased mobility of PFAS in the aquatic environment. For these newer PFAS, the combined properties of aquatic mobility, persistence, potential toxicity and low levels of removal during conventional water treatment processes are considered by some European regulatory authorities (UBA (Germany), ECHA) to pose a threat to drinking water quality.

### 6.1.2 Tonnage, emissions and use

Although there are multiple sources of PFAS in many industrial sectors and the global supply trend is increasing, there is limited information on GB supply volumes and uses. In UK REACH, there are 36 individual PFAS registered with the potential that 40 others could be registered by the final registration deadline. This does not provide the whole picture with respect to the PFAS market in GB as it is likely that some PFAS are manufactured or imported below the UK REACH registration threshold of 1 tonne / per year per manufacturer / importer, or that PFAS are present in finished or semi-finished goods (articles). Table 2.1.2 gives the current UK REACH tonnage.

Considering information from the UK REACH database, three PFAS groups in particular stand out with a wide variety of industrial, commercial and consumer applications:

**Table 6.1.1 High tonnage PFAS groups with a variety of uses registered in UK REACH**

<p>PFAS group</p> <p>(Number of PFAS)</p> <p>Approximate UK REACH registered tonnage (t/y)</p>	<p>Declared uses of UK registered PFAS (and potential terminal transformation products of concern)</p>
<p>Polyfluoroalkyl substances:</p> <p>Hydrofluorocarbons (HFCs), -ethers (HFEs) and -olefins (HFOs)</p> <p>(8)</p> <p>1,000-15,000</p>	<p><u>Industrial uses:</u></p> <p>Manufacture of fire extinguishers and fire suppression systems</p> <p>Refrigerant Gas (heat transfer fluids) - including recycling/reclamation/destruction of waste/F-gas, manufacture of air conditioning systems</p> <p>Foaming agent</p> <p>Laboratory chemicals</p> <p>Industrial use as a monomer (polymerisation)</p>

	<p>Intermediate in the manufacture of fine chemicals, rubber products and plastics products;</p> <p>Washing and cleaning products  Manufacture of fabricated metal products, except machinery and equipment  Manufacture of computer, electronic and optical products, electrical equipment</p> <p><b>Professional uses:</b></p> <p>Fire extinguishers  Laboratory use  Refrigerant Gas (inc. Installation, servicing and maintenance of equipment etc.)  Foaming agent in the building and construction industry  Solvent/cleaning agent</p> <p><b>Consumer uses:</b></p> <p>Aerosol &amp; MDI (metered dose inhaler) propellant</p> <p><b>(PFBA, PFHpA/PFHxA, 6:2 FTOH, PFPA, PFEA, TFA)</b></p>
<p>Perfluoroalkanes and perfluorocycloalkanes  <b>(10)</b>  <b>200-2,000</b></p>	<p><b>Industrial uses:</b></p> <p>Semiconductors  Laboratory Chemicals  Cleaning/etching agent  Solvent in polymerization process  Calibration of analysis equipment  Coolant and detector fluid  Intermediate</p> <p>Non-metal-surface treatment products  Use of non-reactive processing aid (no inclusion into or onto article) in the manufacture of bulk, large scale chemicals (including petroleum products)</p> <p>Applications in the medical field</p> <p><b>Professional uses:</b></p> <p>Refrigerant gas - Heat transfer fluids (including installation, servicing and maintenance of equipment etc.)</p>

	<p>Laboratory Chemicals</p> <p><u>Consumer uses:</u></p> <p><b>Refrigerants Hydraulic fluids</b></p> <p>Heat transfer fluids</p> <p><b>(None)</b></p>
<p>Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H, and O (not including HFCs, HFOs, HFEs)</p> <p><b>(3)</b></p> <p><b>100-1,000</b></p>	<p><u>Industrial uses:</u></p> <p>Manufacture of contact lenses Manufacture of rubber products Manufacture of plastics products Health services</p> <p>Polymer preparations and compounds - Manufacture of plastics products</p> <p>Textile Finishing - Manufacture of textiles, leather, fur</p> <p><u>Professional uses:</u></p> <p>Washing and cleaning products</p> <p>Cosmetics, personal care products/Hair and Cosmetic shops</p> <p>Health services</p> <p>Polymerisation/Intermediate - Manufacture of plastics and rubber products, coatings and paints, thinners and paint removers</p> <p>Polymer preparations and compounds, textile dyes, and impregnating products</p> <p>Textile Finishing - Manufacture of textiles, leather, fur</p> <p><u>Consumer uses:</u></p> <p>Washing and cleaning products</p> <p>Cosmetics / personal care products</p> <p><b>(PFBA, PFPA, PFEA, PFHpA/PFHxA, 6:2 FTOH, 5:FTOH)</b></p>

It is not possible from the registration information to ascertain the tonnage per use/sector. As described in Section 2, the tonnages range from 1 to 15,000 tonnes

per year for registered substances, however, information available for lower tonnage substances suggests these have a narrow/specific type of application. The direct human exposure via consumer use of these substances is of concern, particularly in washing and cleaning products, cosmetics and personal care products. This also results in numerous small but hard to control releases into the environment. A further concern is that the number of potential sites/populations using these substances, the patterns of exposure and incorporation of PFAS into multiple products indicates wide dispersive use.

The data on PFAS emissions are limited. In UK REACH, a detailed exposure assessment is only required for registered PFAS when the tonnage is above 10 tonnes per year and where associated hazards have been identified. Therefore, an estimation of likely releases can only be considered as indicative of relative volumes between PFAS groups, rather than reliable estimates of quantities present in the GB environment. The methodology followed to calculate emission can be found in Section 2; this was used to provide an indicative ranking of potential releases for the PFAS groups (Table 2.3.1).

In terms of the groups of substances identified above in Table 6.1.1 as high tonnage with a variety of uses, these group are all also highly ranked for emissions to air, soil and water within Table 2.3.1.

As information on specific substances or tonnages used in GB is not yet available, emissions by sector could not be directly compared with the declared tonnage of PFAS groups. However, Table 2.3.2 gives the estimates by industry sector with textiles, upholstery, leather, apparel and carpets; electronics; construction; medical devices and medicinal products; food contact materials; and FFF all having high estimated emissions (Table 2.3.2) with respect to water and land. F-gases have the highest estimated release to air.

There are uncertainties in the data for a number of reasons:

- Tonnages for registered substances are for all uses of PFAS and not for specific applications.
- If a substance is placed on the market in GB at less than 1 tonne/year per manufacturer/importer, registration is not required, so we do not have information for numerous smaller uses that could contribute to emissions and use patterns in GB.
- Polymers and (except under certain circumstances) substances in articles also do not have to be registered. Emissions from polymers could be quite significant but could not be quantified in this RMOA.
- Data on emissions cannot be verified from monitoring data, and no modelling was carried out. The data were based on default emission factors which are

conservative and assume the worst-case scenario without considering the specific operational conditions or risk management measures (ECHA, 2016).

Accepting the uncertainties in the data, certain groups of PFAS do stand out because of their high tonnage, numerous uses with potential for wide dispersive use and consumer application. It is also estimated that their applications constitute some of the highest emissions by tonnage. However, it is not possible to read tonnage directly across to emissions. These substances are:

- Polyfluoroalkyl substances: Hydrofluorocarbons (HFCs), -ethers (HFEs) and -olefins (HFOs)
- Perfluoroalkanes and perfluorocycloalkanes
- Polyfluoroalkyl substances: Fluorotelomer-based substances with only C, H, and O (not including HFCs, HFOs, HFEs)

### 6.1.3 Exposure

PFAS substances are known to be ubiquitous in daily life, both in GB and globally – this is due to their presence on the UK market. PFAS have been manufactured or imported into the UK for over 90 years (Environment Agency, 2021). Additionally, the persistent nature of PFAS means that legacy substances that are now controlled or banned are still pervasive in the environment and can also be found in both biomonitoring samples taken from humans and in wildlife. Although both PFOS and PFOA are now globally restricted as POPs, legacy contamination and pollution incidents associated with their uses continue to emerge.

PFAS have been detected at elevated levels in soil or water associated with the use of fire-fighting foams at Guernsey Airport (1999) and Buncfield Fuel Depot (2005). Significant pollution incidents have also been documented over the last 20 years in the USA, Australia, the Netherlands, Belgium, Germany, Sweden and Italy. These incidents were linked to PFAS manufacture, use and subsequent waste disposal by industry, or to the use of PFAS-containing fire-fighting foams. Some PFAS-contaminated land has become unusable for agriculture (Germany) (Brendel *et al.*, 2018).

Details of known declared uses of UK REACH registered PFAS that can be found within consumer products are detailed within Table 2.1.2. However, there are information limitations regarding the full extent of the PFAS used across the scope of consumer products. Additionally, exposure implications are not fully understood and more information and evaluation are required.

The Agency was unable to identify current volumes of PFAS actually entering the GB environment and the main routes, but Section 3 of this RMOA demonstrates that exposure of humans and environmental receptors is occurring.

The key applications that have been identified as major primary sources of PFAS into the environment are industrial processes, fire-fighting applications and consumer products. The exposure pathways to these applications can be summarised as:

- Environmental exposure – solid waste streams with disposal via landfill, sludge spreading to agricultural land or incineration. Liquid waste streams with disposal via wastewater treatment works discharges and direct discharges to surface and ground water. Run-off into drainage systems and surface waters from intentional use of fire-fighting foams in training or response, or absorption into soils and groundwaters from this activity.
- Occupational exposure – inhalation and dermal exposures relating to manufacture in the workplace, professional use and/or application of chemicals (chrome plating or aqueous film-forming fire-fighting foams)
- Consumer exposure – inhalation, dermal and oral ingestion following direct use of products containing PFAS (cleaning products, cosmetics etc.) and contact with products impregnated or treated with PFAS (water/stain resistant products in textiles, food packaging). In addition, indirect exposure occurs via household dust created from products present within homes (Weiss *et al.*, 2021).

There is widespread human and wildlife exposure to some types of PFAS within GB via surface waters and groundwater. Monitoring undertaken by the Environment Agency since 2014 suggests some PFAS are now likely to be detectable in most groundwater, surface water bodies and biota in England (Environment Agency, 2021). Details of the monitoring are covered in Section 3, however, general conclusions that can be drawn are:

- At a grouping level, the detection of multiple precursors to the legacy contaminants, alongside groups that contain replacement PFAS (e.g. fluorotelomers as replacement to PFASs in Aqueous Film-Forming Foam, or PFECA replacing PFOA as processing aids) demonstrate the complex mixture of PFAS that are present.
- The detection of substances that are unrelated to any currently UK REACH-registered precursor or arrowhead substances indicated that these substances are entering the environment through unidentified sources and use.
- Short-chain PFAS are more mobile, likely to be present in water compartments and have greater potential to bioaccumulate in air-breathing organisms through protein driven mechanisms.
- Long-chain PFAS are more likely to be associated with sediments and have a greater potential to bioaccumulate in aquatic and air-breathing organisms through lipid-driven mechanisms.

- PFAS detected in the GB environment are or were intentionally manufactured as commercial chemicals, and some of them are also breakdown products of other PFAS.
- Environmental monitoring data demonstrate that many PFAS are mobile in the environment, indicating the potential for them to travel far from source and then to cycle further.

The unique physico-chemical properties of many PFAS (particularly their oleophobic, hydrophobic and surfactant properties) make the prediction of environmental fate and distribution complex, which has consequences for predicting exposure concentrations. In addition, there are also other uncertainties with respect to the monitoring and detection of PFAS:

- For arrowhead substances, it is impossible to determine how much of the amounts detected in the environment are present because of a specific use of that substance itself, or use as a component in a commercial mixture, or because the arrowhead is present because it is a breakdown product of a precursor substance, an intermediate transformation product or an impurity in another substance.
- The data forms only a partial picture of PFAS present in the GB environment and where they might have originated from based on specific groups.
- There are limitations in analytical methodology which mean the full extent of PFAS contamination is not yet understood.
- Limited temporal trends have been identified but are very difficult to explain with comparison against uses, primary and secondary exposure routes, environmental fate, etc.

With respect to human exposure, aside from occupational settings, exposure could occur through contaminated drinking water, food (seafood, meat, dairy and plants), inhalation of indoor air/dust and dermal absorption through contact with materials and textiles impregnated with PFAS. Consumers will also use goods (such as cleaning products) and be exposed to products containing PFAS such as carpets and clothing. COT and others have suggested that concerns about concentrations in household dust, air, food and food packaging may need further research to understand the significance of these additional sources.

An EFSA (2020) report, which was recently reviewed by COT (2022), raised concerns that exposures to PFAS in household dust could push exposures for infants, toddlers and children over the tolerable weekly intake (TWI). The COT also reported that estimated breast-milk exposures of UK infants exceeded the TWI. EFSA, however, noted that intake via breast milk should not be compared with the TWI and that the calculations likely over-estimated exposure via this source.



Furthermore, COT expressed reservations about the general development of the TWI [for food] calculation and cautioned caveats around its use. COT (2022) stated there was considerable uncertainty as to the appropriateness of the derivation of the TWI and of the biological significance of the response on which it is based, which complicated interpretation of the possible toxicological significance of exceedances.

Occupational monitoring has shown quantifiable levels of PFAS in air in workplaces producing PFCAs, and in the blood of workers at several production and manufacturing facilities. Although this points to a possible concern for workers, much of the data comes from studies outside GB and relates to the production and use of legacy PFAS which have now been phased out. It is therefore not clear that the exposure conditions for these workers are representative for current exposure conditions in GB workplaces. Raised levels of long-chain PFCAs (particularly PFNA), and also legacy PFAS that have now been phased out, have been detected in firefighters. An exemption in current restrictions for the use of PFOA in firefighting foams (FFF) placed on the market before 4 July 2020 or used in the production of other FFF means that there may be ongoing exposure to PFOA for firefighters.

Again, there are uncertainties with respect to the data on human exposure as:

- The majority of data for human exposure are focused on legacy PFAS of PFOS and PFOA, which are now restricted in their use. Therefore, although the available evidence suggests body burdens of legacy PFAS are declining in the global population, this cannot be confirmed for the newer PFAS which have replaced those that have been phased out
- There are limitations regarding the information on the full extent of the PFAS used across UK consumer products. Significantly, exposure implications are not fully understood and more information and evaluation are required.
- Degradation of precursor substances into arrowheads in the environment means that there is some uncertainty with respect to actual exposure.
- The extent to which human exposure occurs via dust and air in the home, and via food, when compared to other sources of exposure (e.g. occupational) is unclear.

With respect to the conclusions that can be drawn from the exposure data, in many cases we do not know if the PFAS detected in the environment are transformation products or the substances as they were manufactured and used, meaning that no link can be made from exposure to tonnage and use in GB. Although the monitoring does include 10 arrowheads of registered substances, which could indicate the breakdown of high emissions of these chemicals, this cannot be concluded with any certainty.

The continued presence of PFAS in the aquatic environment is a particular concern. Information on the properties of PFAS and environmental monitoring data

demonstrate that many PFAS are mobile in the environment, indicating the potential for them to travel far from source. If present in groundwater or inland surface waters there is a potential for human exposure via drinking water. There are already some sites in GB where PFAS levels in ground or surface waters (not used as drinking water sources) exceed drinking water standards for some specific PFAS. The available data indicate that it can be difficult to remove PFAS from water using conventional water purification techniques. The extreme persistence of these arrowheads and concern with respect to the mobility and potential bioaccumulation of the short-chain PFAS mean that levels will likely continue to increase over time without further intervention. This risk could be further increased near industrial sites where contamination with PFAS is expected to be more likely.

The use of FFF by fire fighters whilst fighting fires is generally conducted while wearing PPE, again keeping exposure to a minimum, however as PFOA is still able to be used in FFF (placed on the market before 4 July 2020 or used in the production of other FFF), there is potential for exposure to both humans (directly), during clean-up and the environment from run-off into water courses etc.

Most if not all consumers will be exposed to PFAS several times each day owing to the presence of these substances in cleaning products, personal care products and cosmetics. Additional sources of exposure stem from the use of stain- or water-resistant coatings on furniture, clothing, food packaging materials and non-stick coatings on food contact materials such as cookware. PFAS can also be present in house dust giving the potential for inhalation exposure. Exposure to PFAS from consumer goods occurs primarily via the oral and inhalation routes (through indoor air and dust), which could account for up to 50% of the total PFAS intake (Sunderland *et al.*, 2019).

Currently, biomonitoring data to determine PFAS exposure amongst the GB general population are not available. Under the auspices of a European Human Biomonitoring (HBM4EU) / Health Protection Unit (HPRU) study (HBM4EU, 2022), general population samples of blood and urine are being collected, with publication of results expected in 2024. Further work is also being undertaken under the PARC project (Section 3.2.3). Until these data are available, European data can be used as a proxy for GB data. European data on time trends are limited, but data from Germany indicate that serum concentrations of legacy PFAS (PFOS, PFOA and PFHxS) in humans are declining (HBM4EU, 2022) (EFSA CONTAM Panel, 2020); PFNA was also reported to be decreasing in the German study. Nevertheless, PFOS and PFOA were still the substances occurring in the highest concentrations in Europe. EFSA (EFSA CONTAM Panel, 2020) reported that serum/plasma concentrations of PFNA, PFDA and PFUnDA have increased since 2000.

#### 6.1.4 Hazard

The hazards of certain PFAS (primarily the PFAAs) have been well characterised and have resulted in regulatory controls and measures, including, amongst others, UK REACH restrictions and risk management under POPs legislation. To understand the information availability and hazards of less-well documented PFAS, a high-level hazard assessment of selected substances was undertaken; given the large number of substances in the scope of the RMOA, substance and group selection was directed by information on tonnage and emissions, as well as knowledge of GB manufacture and detection data from the GB environment. More details on the approach can be found in Section 4.

The hazards of these other, non-PFAA PFAS have been investigated to varying extents and degrees of rigour depending, for example, on their level of supply. This will have influenced the extent of toxicity testing undertaken by industry for substances on the GB market to ensure compliance with REACH registration requirements.

At the lower tonnages, the extent of testing for regulatory purposes may not have been sufficient to address the hazards that can indicate whether a substance can be regarded as a PBT. Indeed, the high-level hazard assessment undertaken in this RMOA indicated that for some substances (and groups), there was no or only very limited data to inform on their hazardous properties. The unusual chemistry (e.g. surface activity, recalcitrance) of many PFAS also makes them unsuitable for assessment in some standard studies (e.g., octanol water partition coefficients, water solubility, aerobic/anaerobic degradation studies and particularly bioaccumulation).

The primary focus for our human-health toxicity assessment was the endpoints that can lead to the determination of the “T” criterion to aid identification of substances that are PBT. Substances identified as “T” from mandatory classifications, self-classification by the registrant or from the high-level hazard assessment undertaken in this RMOA are detailed in Section 4. A formal hazard assessment, looking in detail at individual studies, was not performed, but this could be an option for future work (for example, for TFA). Although hazard information is available for the key arrowhead substances, this assessment demonstrated that the amount of information on precursor substances is variable and often very limited.

Conclusions that can be drawn with respect to the T criterion for human-health effects are:

- A key concern for some PFAS groups is reproductive toxicity, specifically that they cause adverse developmental effects in laboratory animals. This has resulted in mandatory classifications for reproductive toxicity for some of the arrowhead substances in the long-chain PFCAs and long-chain PFSA groups which result in them meeting the T criterion. Whilst there is no evidence that

any PFAS causes adverse development or reproduction outcomes in humans, EFSA concluded that 'there may well be a causal association' between maternal serum PFOA and PFOS levels and low birth weight. The current assessment highlighted a potential concern for developmental toxicity in laboratory animals for two substances, the arrowhead substance trifluoroacetic acid (TFA) and EEA-NH4.

- Although carcinogenicity has been raised as a concern for PFAS, no substance has been established as a human carcinogen. EFSA CONTAM Panel (2018, 2020) reached the same conclusion, stating that the available human data on PFOA (and PFOS) was insufficient to conclude that either substance was a human carcinogen. There was also no evidence of a link between other PFAS exposure and human cancer risk (COT, 2022; EFSA CONTAM Panel, 2020). There is limited evidence that some arrowhead PFAS (long-chain PFCAs and PFSAs) might have the potential to cause cancer; for example, a positive association between PFOA exposure and cancers of the testis and kidney has been reported (IARC, 2016). For PFAS that have been registered in the REACH framework, only one had a carcinogenicity study, which did not indicate a carcinogenic potential in the laboratory species used. No substance with a mandatory classification for carcinogenicity meets the T criterion on the basis of that classification alone.
- Genotoxicity has not been highlighted as a potential concern for PFAS.
- The liver and kidneys are typically the target organs upon repeated exposure of laboratory animals to PFAS. This is reflected in mandatory classifications for several substances for these effects, and also in some of the data submitted within the REACH framework. Several of these substances (those with mandatory classifications for specific target effects seen in repeat-dose studies and those that meet the criteria for such classification) can thus be identified as T. Regarding effects noted in humans, associations between PFAS exposure and liver function/disease are inconsistent or only modest, whilst an association with kidney function has not been demonstrated (COT, 2022).

Established environmental hazards, PBT and vPvB, and proposed PMT and vPvM were considered in Section 4 in accordance with Annex 13 of UK REACH. Where EA had undertaken informal risk assessments of endocrine disruption in line with OECD 2018, this information was also considered. Most non-polymeric PFAS (or their arrowheads) are both very persistent and very mobile, even if they do not exhibit significant toxicity. Heatmap data in Section 4 (taken only from ECHA and US EPA sources) suggested that there were indications that registered substances within each of the groups were persistent, bioaccumulative, mobile and/or toxic, but the data were often conflicting at group level. Therefore, it could not be concluded that the definitive criteria for PBT, vPvB, PMT or vPvM could be met, but paucity of data was noted as an uncertainty, as well as the inability to draw conclusions from heatmap data at a grouping level.

Although some PFAS have been found to be bioaccumulative using standard studies, these focus on bioaccumulation in lipids. Numerous studies have demonstrated that PFAS may also bind to proteins. The potential for non-lipid based accumulation is not currently part of the standard testing regime.

There are many uncertainties with the hazard data:

- Our assessment represents only a small proportion of the total PFAS family and was based on agreed prioritisation criteria.
- The degree of hazard assessment that could be carried out for the fourteen prioritised groups varied because of information availability. This was partly related to the reliance on EU REACH registration data: data were not widely available for some PFAS groups, for example because substances were not registered or were registered at low tonnages.
- The unsuitability of some standard studies (for instance for bioaccumulation) and questions over the reliability of some of the modelled data for PFAS because of their unusual chemistry.
- The assumption that group-level hazards can be inferred from a relatively small number of substances (five to eight) was not always supported. Although the groups were based on structural similarity, on several occasions data on the representative substances spanned a large range within each group. Some data from substances within groups were conflicting, and the analysis was confounded in some cases by a lack of information; therefore, fewer than the target number of substances were assessed for some groups.
- PFAS (and their arrowheads) have extremely long degradation half-lives. The potential effects as a result of continuous exposure of wildlife in the environment and humans over their entire lifetime is not well understood and is not possible to assess.

With respect to the information evaluated in this RMOA, it is therefore evident that comprehensive hazard data are not available for many substances. From an evaluation of the available evidence, and given the uncertainties listed above, it is not possible to reach a definitive conclusion on the environmental or human-health hazards for most of the PFAS groups considered in this RMOA.

Given the large number of substances that fall within the various PFAS definitions, it is clearly not feasible or desirable, because of animal-welfare, cost and time considerations, to undertake suites of toxicity and environmental studies to more fully investigate the hazardous properties of all these substances. Instead, a common approach to address this issue is to consider arrowhead substances and their precursors as a group, the assumption being that the hazards of the arrowheads will drive the hazards of the group as a whole. Whilst there are some uncertainties associated with this approach (some precursor substances are reported to be more toxic than their final degradation products), it does offer a pragmatic solution.

Overall, therefore, the following statements seem applicable.

- All PFAS demonstrate persistence beyond that of the UK REACH threshold criteria, especially where conclusions are made encompassing their transformation products; this potentially will give rise to increasing concentrations in the environment over time (as noted we do not have any information or ability to test for continuous exposure to the environment and humans over lifetimes).
- The PFAS arrowheads have hazardous properties: as well as environmental effects, a variety of toxic effects have been found with arrowhead perfluoroalkyl acids in studies in experimental animals, and to a lesser extent in humans. Information for other PFAS (including precursors) is generally limited.
- Some arrowhead substances have already been flagged for action both domestically and internationally on the basis of PBT/vPvB properties. Assuming that these substances act as hazard markers for their precursors (noting some uncertainties associated with this approach), it is important to ensure that such precursor substances are included in any actions to manage the risks posed by PFAS as well as the resulting transformation products.
- Not all PFAS groups appear to degrade in the environment to arrowhead PFAAs, or such degradation has not been investigated. For most of the groups assessed in this RMOA that do not appear to degrade, the available hazard information was limited.
- Of the groups prioritised for hazard assessment, the following have PFAAs as their potential final transformation products:
  - Perfluoroalkenes (final degradation products are PFCAs)
  - Side-chain fluorinated polymers, PASA, POSF-based products, PASF derivatives (final degradation products are the respective PFCAs and PFSAs)
  - Perfluoroalkyl phosphonic and phosphinic acids (possible degradation to PFCAs, although limited or no specific information available).
- A potential concern for developmental toxicity in experimental animals has been identified for the arrowhead substance TFA. Some of the substances in the HFCs, HFEs and HFOs group (i.e. a commercially significant, high tonnage group in GB) are F-gases that may transform to TFA.
- On a global basis, only the long-chain PFCA group has been accepted as a POP so far (and is on Annex E of the Stockholm Convention) and as being unequivocally recognised as hazardous. There is recognition, however, that the short-chain PFCAs have PMT and vPvM type concerns, as well as B

concerns. It is expected that other PFAS substances will become POPs so this may help global understanding on acceptance on groups of concern.

### 6.1.5 Alternatives

At this stage it was not in scope to comprehensively analyse all the alternatives for PFAS, given the variety of substances covered in the groups and also the multitude of different uses. This RMOA focused on the main alternatives with respect to whether they can perform the technical functions provided by PFAS at a general level, and what hazards may be associated with these alternatives. The information was primarily taken from three OECD reports (OECD, 2020, 2022a, 2022c) and information provided in the GB call for evidence.

From what could be concluded, there are alternatives to PFAS in many applications, particularly in the simpler consumer uses, although more complex industrial applications may be more challenging and require further research with respect to requisite performance e.g., fluoropolymers and fluoroelastomers are mentioned specifically in the call for evidence. Cost is also mentioned as a concern by industry, which would also need more detailed impact assessment.

A key consideration is that for some alternatives, there may be inadequate hazard information, or the hazard profile of the potential alternative could mean other risks are introduced into processes and uses which may not be cognisant with the aim of the application. For instance, in looking at the replacement of PFAS used in stain/water resistance, the replacement substance could adversely affect the flammable nature of the fabrics or other substrates that they are applied to. With respect to fire-fighting foams, it could be that alternatives may have fewer long term hazard concerns but a more detailed analysis of performance is needed in some use sectors, e.g., petrochemicals. One of the challenges of substituting PFAS is that their persistence in the environment is due to the presence of the strong C-F bond, which at the same time, along with their high electron affinity, contributes to their desired properties, thus leaving fluorine-free alternatives compromised in terms of performance.

In conclusion, although only a high-level analysis has taken place, there do appear to be potential alternatives to PFAS for many uses. However, more performance and socioeconomic information will be required to ensure that alternatives are technically and economically feasible and are able to meet performance standards. Hazard information for alternatives also needs further investigation to avoid regrettable substitution (such as PFOS with PFOA).

Potential risk management measures will need to take into account the challenges of substitution and the need for this to take place across different pathways and timescales, in accordance with the releases and exposures across sectors and uses.

### 6.1.6 Regulation

PFAS in the scope of this RMOA are regulated to a certain extent within GB and this is described in more detail in Section 5, along with information on what actions other countries are taking on PFAS internationally.

#### **GB**

With respect to the GB regulatory framework, there are a mixture of regulations. Some, such as health and safety legislation like COSHH, are quite general and goal-setting in their approach – with specific limits or the edict to keep exposure “as low as reasonably practicable” where there are specific hazards associated with the substance. There are no WELs for PFAS substances; for this to be considered more information on use, exposure and hazard would be needed.

The GPSR is similarly broad in that all PFAS-containing products are in scope but lack of hazard data for many of the groups mean that it is difficult to deem which, if any, products could be regarded as unsafe.

For drinking water, standards for certain substances can be set, and as a general principle drinking water should be “wholesome” as defined in the Water Supply (Water Quality) Regulations (2016, England/ 2018, Wales). For England and Wales there is some additional guidance on PFAS in water, including a wholesomeness guideline value of 0.1 µg/l for any of the 47 individual PFAS listed in Information Letter 05/2021. However, there are currently no statutory drinking water limits for PFAS in England and Wales.

There are no specific restrictions on PFAS with respect to food and food contact materials. Any materials and articles that use PFAS must meet the legislative requirements set out in the Materials and Articles in Contact with Food (England) Regulations 2012, with parallel legislation in Wales and Scotland, with respect to ensuring that they are safe in expected use. PFAS are on the Food Standards Agency’s Risk Analysis Issues Register and this may lead to other activity after further risk analysis.

Environmental legislation introduces Environmental Quality Standards (EQS) for priority hazardous substances to try to eliminate emissions.

There is ability to assess which substances are hazardous to groundwater. Of all of the PFAS considered in this RMOA, only PFOS has currently been considered for this risk. There is also the requirement for GB environmental regulators to issue a permit to waste sites and industrial installations where listed “polluting substances” are emitted, this permit can include reporting conditions and there are some in place in GB for sites that make or use PFAS.



Some PFAS are covered by the fluorinated gas (F-gas) regulation and will be subject to the internationally agreed phasedown of hydrofluorocarbons. This includes five substances belonging to two PFAS groups (Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs) and Perfluoroalkanes and perfluorocycloalkanes) with another in the first category subject to monitoring and reporting.

PFAS in scope of this RMOA are used in detergents as surfactants, the Detergent Regulations establish rules for the biodegradability of such substances in detergents. This legislation also gives the ability to ban or restrict certain detergent surfactants, however there are no PFAS substances banned or restricted currently under this regulation.

For UK REACH, there are existing measures in place, with some PFAS in scope of this RMOA already identified as Substances of Very High Concern (SVHCs) but none have yet been placed on the Authorisation List (Annex 14). UK REACH restrictions are in place for two PFAS substances, PFOA and its salts and perfluorinated silane. The Persistent Organic Pollutants (POPs) regulations, which implement the UN Stockholm Convention, restrict the use of PFOS and eliminate the use of PFOA and its salts. As PFOA is listed as a POP, the UK REACH restriction will be revoked as it has been superseded by the POPs restriction. Recently PFHxS, its salts and PFHxS related compounds have also been added as a POP for elimination via a POPs restriction. A recommendation for listing as a POP is also expected for long-chain (C<sub>9</sub>-C<sub>21</sub>) PFCAs. As bans initiated under the Stockholm Convention on substances classified as persistent organic pollutants (POPs) take effect in the UK as a signatory to the convention, it is not thought that further action under UK REACH is required for these substances at this time.

It can be concluded that although there are measures in place within the GB framework, there are certain gaps in regulation for both consumer exposure (products and coatings, drinking water and food contact) and environmental control with emissions only controlled at source for certain installations and an EQS only in place for one individual PFAS in scope of this RMOA.

### **International - EU**

Looking to the global management and regulation of PFAS, there are risk management measures in train in the EU, such as an EU REACH restriction which came in to force last year for long-chain (C<sub>9</sub>-C<sub>14</sub>) PFCAs due to concerns on PBT and vPvB properties, which aims to avoid regrettable substitution of PFOA. Both this and a proposal to restrict PFHxS, its salts and related substances are the subject of an agreed POPs hazard listing and an agreed POPs restriction respectively so any EU REACH restriction would be revoked anyway once adopted fully into POPs legislation.

Another proposed REACH restriction currently at the decision stage in the EU is on PFHxA on the basis of (amongst other things) extreme persistence, mobility and adverse effects in developmental toxicity studies. At an earlier consultation to identify PFHxA as an SVHC (which was withdrawn), the UK (as an EU Member State) raised observations about the claimed hazardous properties. It is noted within the actual restriction dossier that no additional data are provided on these properties which would clarify our original concerns or result in PFHxA being classified as toxic or very bioaccumulative. **The main concern based on the conclusion of this RMOA would be with respect to degradation to the arrowhead substance.**

Two REACH restriction proposals are currently being developed by ECHA, the first is a proposal to restrict PFAS in AFFF – this is on the same hazard basis as the PFHxA but is to prevent regrettable substitution of PFOA AFFFs and to tackle the known risks from FFFs. As noted in both Section 2 of this RMOA on use and Section 3, there are concerns regarding the wide dispersive uses of PFAS, high exposure and levels of relevant PFAS arrowheads/groups from monitoring as well as the mobility of substances through the water compartment which has been flagged by high levels in drinking water. The second restriction is a very broad scope restriction proposal for all PFAS in scope of the OECD definition, as noted in Section 1 we are using a different definition of PFAS in this RMOA.

Other relevant EU legislation on environmental aspects such as the Water Framework Directive, Groundwater Directive and management of drinking water could be considered such as a wider EQS for PFAS. Although analytical methods exist for a number of individual PFAS, methods do not yet exist that would allow evaluation of a “PFAS total”. The EU has recently issued recommendations on PFAS in food on the basis of an opinion from EFSA – this has been reviewed by COT (2022) and further action may be considered by the Food Standards Agency.

**Additionally, the European Commission has reviewed and revised the F-Gas regulations and is proposing to go beyond the current HFC phasedowns and introduce new bans. This could be considered in GB, however this is only applicable to certain groups of substances in scope of this RMOA.**

### **International – USA**

Action is being taken as part of a national PFAS Action Plan (see Section 5). Much of this Action Plan is of interest with respect to a wider plan on PFAS from a GB policy point of view. The USA has also released a PFAS roadmap. Some measures are similar to those mentioned above with respect to action on drinking water, however specific drinking water regulations are being put in place for PFOA and PFOS. They can also restrict discharges at industrial sites, which is similar to the environmental permitting in place in GB but possibly on a wider scale.

The USA has also taken steps to increase the amount of information on PFAS through enhanced reporting requirements and is consulting on the collation of all

existing information on PFAS, as well as undertaking a national PFAS testing strategy. Additionally, the USA has ended low volume exemptions and will review risk assessments for new chemicals before they enter the marketplace, with unreasonable risks required to be mitigated before manufacture can commence. At a federal level there are also controls of FFFs in the USA with a phase-out of all PFAS FFF by October 2024.

Information gathered and made publicly available by the USA will be extremely useful in looking at any additional risk management required for PFAS. Other measures on the evaluation and pre-market restriction for low volume substances would require a change to the GB regulatory system or a new specific approval system for PFAS which is not in line with current regulatory policy and innovation goals.

### **International – other**

Other countries such as Canada, Australia, Japan and China have also taken measures on PFAS:

- In 2016, Canada prohibited the import, manufacture, use and sale of PFOS, PFOA, and other long-chain PFCAs (and salts and precursors).
- Australia has begun phasing out its use of PFOS and PFOA containing AFFF and has a national environmental management plan which primarily deals with contaminated sites, they also require an application to the authorities if PFAS (4-20 perfluorinated carbons) is to be “introduced” above 10 kg per year as it is automatically a medium/high risk for human health and the environment.
- In Japan, PFOS and its salts are listed under control laws and subject to an export restriction.
- In China there is a ban of production, transportation, application, imports and exports of PFOS, its salts and PFOSF, except for specific exemptions and acceptable use as well as restriction of the production of PFOS and PFOA.

To conclude, it is clear that PFAS is a global issue of concern with countries with embedded regulatory regimes taking steps to control PFAS. Information from these systems will be reviewed as it becomes publicly available in order to inform any chemical risks which need to be addressed in GB. The strategic consideration of PFAS to bring together strands of work would be a useful way of joining up the various concerns on PFAS, as there are other aspects such as decontamination, food contact materials and public health which could form part of an overarching picture that would need buy-in from all sectors. This would be consistent with work Defra has been undertaking on strategic policy development across a range of chemicals issues that builds on government’s commitment in the 25 Year Environment Plan to set out our strategy to tackling chemicals of concern.

## 6.2 Identification and assessment of risk management options

### 6.2.1 UK REACH

UK REACH requires registrants to demonstrate that their substances can be used safely. If a PFAS is supplied above 10 tonnes/year and identified as hazardous then a risk assessment is also required to be conducted. As noted in Section 2 there are 36 PFAS substances registered under UK REACH. However, this does not cover import in articles and substances manufactured or imported in quantities under 1 tonne per year.

The baseline against which additional risk management options have been assessed is the registration of PFAS under UK REACH. This represents the situation if the UK takes no additional regulatory action.

#### **Evaluation of substances**

UK REACH Substance Evaluation (SEv) has the potential to compel industry to generate the additional information needed to clarify concerns beyond the standard UK REACH information requirements of specific registered substances, which may subsequently lead to further risk management being justified. The onus is on the Agency to justify the data requests, which must be clearly linked to an identified concern and likely to improve current risk management measures. This takes a considerable amount of resource, and can also be subject to legal appeal. Although not a risk management option in itself, being able to conduct evaluations and to request more information if necessary, could filter into other measures such as SVHC identification.

Informal environmental assessments (unpublished) were conducted by the Environment Agency between 2020 and 2022 of 8 UK REACH-registered PFAS that were manufactured or imported into the UK, plus 1 unregistered PFAS found in UK water monitoring. These identified where additional information or data would be help in our understanding of their physico-chemical properties, hazards and in some cases their environmental sources, emissions and exposure. Some of these gaps could be addressed via UK REACH registration compliance check activities by the Agency, although this is limited to the standard information requirements relevant to the registered tonnage.

Substances can also be evaluated and subsequently managed in groups. This could involve taking an 'arrowhead' approach, whereby arrowhead substances and their precursors are considered together, with the hazards of the arrowheads driving the hazards of the group as a whole.

Formal evaluations undoubtedly could play a role in delivering a suite of risk management measures to address the risks presented by PFAS. The additional evidence and knowledge collected could drive some PFAS towards being regulated under one particular measure or another. However, a significant downside is that the

time required to evaluate, produce formal decisions, have the new data generated and then evaluate the new evidence base could take 3-4 years or more. There might be a number of lower priority PFAS groups - such as perfluoroalkanes and perfluorocycloalkanes - that do not degrade to arrowheads of concern, where SEv might usefully clarify whether hazards exist and where risks from slower action could be acceptable. These substances are high tonnage substances in GB so this could be a useful measure to look at these PFAS more closely. SEv is also only relevant to PFAS which have been registered by at least one UK REACH registrant so will only address those that are supplied at over 1 tonne per year.

### **REACH Authorisation (including Candidate Listing)**

Under UK REACH, substances can be identified as substances of very high concern (SVHCs) if they meet one or more of the hazard criteria outlined in Article 57. When a substance is identified as an SVHC, it is added to the Candidate List. This is a list of substances which may be considered for inclusion in Annex 14 of UK REACH (the Authorisation List). Duties to seek authorisation to use substances or else find alternatives only apply when substances have been added to the Authorisation List – the onus is on the Agency to identify new SVHCs and consider recommendations to the Authorisation list to be put forward to the Appropriate Authorities.

HFPO-DA, PFBS, PFHxS and C<sub>8</sub>-C<sub>14</sub> PFCAs (and various salts) are identified as SVHCs on the UK Candidate List. PFHxS and the long-chain PFCAs are all subject to POP nominations, so authorisation would potentially conflict with the outcome of that process. HFPO-DA and PFBS could be considered for inclusion on the UK Authorisation List, but neither is UK REACH registered and there are no current known uses in GB, but should more information become available on use this could be considered in the future. PFBS may be present in surface coatings on imported articles, but these uses are not within the scope of the authorisation regime. In addition, both are listed on the basis of “Equivalent Level of Concern” and it is currently unclear whether an authorisation application could be made using the adequate control route for this type of concern.

It is likely that more PFAS will be found to meet the Article 57 SVHC criteria in due course, once further information is gathered. Some of these may be suitable candidates for authorisation.

Authorisation does not apply to chemical intermediates and some PFAS in scope of this RMOA are used as intermediates, so therefore authorisation is not a suitable option to manage any risk from this use. The authorisation of PFAS would encourage substitution, but where industry considers this cannot currently be achieved it allows companies to apply for continued use in specific applications. Authorisation has the potential to allow uses where there is a net benefit to society where there are no suitable alternatives, whilst creating pressure to move to alternatives but minimising the possibility of regrettable substitution. Authorisation

would require companies to broadly consider the comparative hazards and risks of alternatives, which may include (but is not limited to) the alternatives described in Section 2.4.

If authorisations were to be granted, in the short to medium-term it is likely that there would be continued release of PFAS into the environment subject to any measures put in place to reduce emissions to as low as technically and practically feasible. In addition, if PFAS are not added to Annex 14 promptly, authorisations may be delayed in having an effect. This could be countered by consideration of fast-track authorisations if appropriate. In granting authorisations, the costs (both economic costs to applicants and environmental costs of continued release) and benefits for each use would be assessed on a case-by-case basis. This would be particularly helpful for sectors where alternatives need to undergo safety testing before they could be introduced or where new substances are being developed and information on hazards and efficacy for these new substances is still being generated. Given the cost of preparing and applying for an authorisation, it is expected that where substitutes are readily available companies will substitute.

Authorisation would not apply to imported articles containing PFAS, such as textiles and electrical equipment. Instead, in accordance with Article 69(2) imported articles would need to be considered to determine if they are a significant source of PFAS in the environment which pose risks that are not adequately controlled. If they are, it will be necessary to develop restrictions accordingly.

The Agency considers that based on the current information, UK REACH authorisation is unlikely to be an effective regulatory tool to minimise PFAS emissions, primarily because of the time required to take substances (or groups) through the SEv process to enable SVHC identification, and the limited number of PFAS that might end up being SVHCs under the current criteria due to the uncertainty on the hazard profile of many of the PFAS groups. Authorisation would be ineffective in minimising releases associated with imported articles, would not be applicable to article service life losses or use as chemical intermediates. Authorisation might be useful in very limited circumstances where there are an apparent a lack of viable alternatives within a relatively narrow process, such as minimisation of PFAS processing aid releases from fluoropolymer manufacturing sites. The Agency could look at the SVHC listing and subsequent authorisation as a result of this RMOA.

### **Restriction**

Restrictions can be introduced when there is an unacceptable risk to human health or the environment arising from the manufacture, placing on the market and use of a substance. When considering a restriction on a substance, the scope is assessed in terms of effectiveness, practicality, monitorability, alternative substances and techniques, and socio-economic impacts.

Restricting certain PFAS could address emissions arising from substances, polymers and articles both imported and manufactured within the UK. However, the lack of information on the actual types and quantities of imported articles and costs/feasibility of using other substances or technologies would need to be addressed to enable cost-benefit assessment. So as part of any proposal to restrict the Agency would need to seek more reliable hazard, use, emission, and exposure information, together with socio-economic data and information on alternatives.

Any restriction proposal for PFAS would require an assessment of alternatives for all uses that fall within the scope of the restriction. Consideration would need to be given to availability of substitutes, their cost and effectiveness compared to the substituted PFAS, their hazard properties, and timescales for product safety testing and re-certification.

Restrictions that place limitations on the supply and use of PFAS would need to take account of the difficulties separating materials that may contain PFAS at the waste sorting stage, and the economic benefits of recycling materials which may contain greater concentrations of PFAS than is desirable in new materials. Although specific derogations for recycled material may be a possible solution, there could be difficulties in enforcement if there are different requirements for recycled and new materials. An example for consideration in this area is the recycling of paper and board containing PFAS.

The Agency has concluded that, based on the information gathered in this RMOA, a targeted restriction or a number of targeted restrictions would be a more effective regulatory option than authorisation for minimising releases of PFAS to the environment, including from polymers and imported articles and looking at substances of concern due to wide dispersive use, high emissions or indications from monitoring data. The preparation of any restriction dossiers would require substantial resource, in particular to refine emission estimates to ensure the targeting is appropriate, and data gathering for a socio-economic analysis, taking into account the availability and technical performance of alternative substances.

Several further PFAS restrictions are under consideration by the EU, these are covered in Section 5 and are discussed further above, the targeted restriction on FFF has been identified as one of interest for a UK REACH restriction due to commonalities in use and exposure.

### 6.2.2 Other regulations for potential consideration

There are other regulations in GB which are not part of the framework which currently regulate PFAS or which could be extended to cover PFAS more specifically.

### **GB Classification and Labelling regulations 2008 (as amended):**

Substances and mixture placed on the market in GB must be classified and labelled in accordance with the GB CLP regulation. Substances included on the GB mandatory classification and labelling (MCL) list have legally binding (mandatory) classification and labelling requirements in GB.

The GB MCL list is updated to include additional substances or to revise existing entries. Such updates arise in response to opinions on EU harmonised classification and labelling (CLH) from ECHA's Risk Assessment Committee (RAC) or from the Agency's own proposals (i.e., Articles 37 and 37A of GB CLP respectively). For TFA and EEA-NH4, the available data raise concern for reproductive toxicity and consideration of a new (for EEA-NH4) or revised (TFA) entry in the GB MCL list would be a key step in addressing uncertainties.

If a new/revised GB MCL entry is agreed, the classification could also prompt other measures in REACH such as SVHC listing and the recognition of certain risk management and control with respect to use.

### **The Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment Regulations 2012 (as amended)**

Some uses of PFAS in electronic equipment are likely to fall within scope of the RoHS Regulations. The regulations restrict (with some exceptions) the use of listed (Annex II) hazardous substances in the manufacture of various types of electronic and electrical equipment. PFAS are not currently listed as restricted substances under RoHS.

The Agency considers that the RoHS Regulations provide a potentially effective regulatory option for a very restricted domain of applicability. It could be a parallel measure to a UK REACH restriction, but no specific environmental or human health risks have been identified from consumer electrical and electronic equipment. The Agency considers, therefore, that it may be more efficient to tackle this PFAS source as part of a UK REACH restriction, though the two regulatory instruments are not mutually exclusive.

### **The Persistent Organic Pollutants (POPs) Regulation 2007 (as amended)**

Some PFAS groups that meet the REACH Annex 13 PBT/vPvB criteria may also fulfil the POPs criteria, with atmospheric transport on airborne particulates providing a potential route for long-range transport. Some PFAS have been detected in environmental samples from remote (Arctic) regions.

POPs listing is a potentially applicable and effective risk management option for any PFAS meeting the Annex D criteria, since it would apply across the globe, thereby minimising the likelihood of substances entering the UK in articles and semi-finished goods in future. It could be advantageous to work collaboratively with other countries



that are currently contemplating action on PFAS. PFAS is a global issue, so a consistent global response would be appropriate. However, for most PFAS groups there is currently insufficient evidence that the Annex D criteria are met. Additionally, it would not apply to PFAS meeting the putative PMT/vPvM criteria unless there is also evidence of significant bioaccumulation. The Agency concludes that this risk management measure would not be feasible for most PFAS groups in the short to medium term but may have potential for individual PFAS and some key groups.

### **River Basin Management Planning**

Identification of further PFAS as priority substances or (more likely) priority hazardous substances for surface waters would require the UK Government to establish corresponding EQSs, through the UK Technical Advisory Group (UKTAG). This would then oblige the Environment Agency, NRW and SEPA to plan and deliver programmes of measures to achieve the EQSs, where it is technically feasible and not disproportionately costly to do so. For any PFAS designated as priority hazardous substances, the UK would also have to carry out measures for the cessation or phasing out of discharges, emissions and losses to the aquatic environment.

New EQS for further PFAS in surface water could be set in future under the Environment Act 2021<sup>38</sup>.

Determination of whether further PFAS are hazardous to groundwater or not could also be a further option for risk management with links to environmental permitting.

Statutory EQS designation has driven extensive monitoring investigations by the sewerage utilities (under the Chemicals Investigation Programme) that is improving understanding of both indirect releases via the sewerage network and background contamination. This, and the potential cost to the sewerage utilities of enhanced sewage treatment to meet prospective permit limits, has increased the sector's interest in emission sources and could be expected to lead to more effective trade effluent control. However, permit limits for UK sewerage utilities would be determined by consideration of EQS compliance and "no deterioration" in water quality. There are significant technical challenges to removing PFAS from wastewater and to reliably measuring PFAS concentrations in environmental media. Wastewater treatment techniques may also not result in prevention of PFAS from entering the environment, but entry to river basin catchments via different routes such as materials spread on land.

PFAS permit limits would also potentially apply to direct discharges to water from industrial sites. Many larger sites are regulated under the Pollution Prevention and Control (PPC) Regulations and Environmental Permitting Regulations (see below), in

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<sup>38</sup> <https://www.legislation.gov.uk/ukpga/2021/30/contents/enacted> (Accessed November 2021).

which case Best Available Technology considerations would apply to releases. River basin management planning could, however, provide some impetus for emission reductions with respect to smaller industrial sites that are out of scope for PPC.

The Agency has concluded that as well as providing a potential monitoring tool, river basin management planning environmental permitting routes have potential to minimise legacy PFAS that have already been used from entering the environment with PFAS emission reduction within the medium to long-term. However, this will consume resources from the GB regulatory authorities and water companies (with costs passed to water customers and regulated industries discharging PFAS) much more than from the suppliers of PFAS, in conflict with the polluter pays principle.

### **The Environmental Permitting Regulations and Pollution Prevention and Control Regulations**

These regulations are discussed in more detail in Section 5 and require operators of industrial installations to obtain a permit from the national authorities to continue operating. **The PPC regulations, implemented through environmental permitting requirements, have the potential to limit PFAS emissions from permitted sites that manufacture, process or use PFAS.** However, permitting will have no effect on the service life emissions or releases from the disposal of articles containing PFAS. The Agency has concluded that environmental permitting already provides a means for limiting PFAS emissions from sites that manufacture, formulate/process or use PFAS, but appears to offer little scope for further risk management.

### **Waste management legislation**

Waste regulations set out the basic requirements for the management of defined wastes using a hierarchy approach to ensure recovery or disposal without risk to water, air, soil, plants or animals. Costs are borne by the waste producer or waste holder.

For a PFAS classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H401) under the CLP Regulations, any waste mixture containing it at a concentration above 0.25% w/w would be considered to be hazardous waste. Waste treatment facilities must obtain permits from the relevant competent authority, which specify technical and other requirements for each type of operation permitted, as well as the safety and precautionary measures to be taken (with monitoring conditions where necessary). Waste management plans must be produced by regulatory authorities, which may include economic and other instruments to tackle various waste problems, and awareness campaigns directed at specific sets of consumers. There are no provisions for information gathering.

The Agency has concluded that the waste regulations would not be very effective for minimising PFAS emissions and environmental exposure, although they could reduce exposure from certain waste streams.

## **The Fluorinated Greenhouse Gas Regulations**

This RMOA has identified volatile PFAS that are UK REACH registered but not included in either Annex I or Annex II of the F-gas Regulations in table 6.2.1 .

**Table 6.2.1: UK REACH registered volatile PFAS not included in Annex I or II of the F-gas Regulations**

<b>PFAS</b>	<b>CAS No.</b>	<b>PFAS Group</b>
Ethene, 1,1,2-trifluoro-2-(trifluoromethoxy)-	1187-93-5	Perfluoroalkyl ethers (PFE), epoxides & vinyl ethers
Hexafluoropropene (1-Propene, 1,1,2,3,3,3-hexafluoro-)	116-15-4	Perfluoroalkenes
3,3,4,4,4-Pentafluorobut-1-ene	374-27-6	Polyfluoroalkyl substances: hydrofluorocarbons (HFCs), -ethers (HFEs), -olefins (HFOs)
(Z)-1-Chloro-2,3,3,3-tetrafluoropropene	111512-60-8	Polyfluoroalkyl substances: halides (i.e. iodide, chloride and bromide)

It is concluded that these PFAS could be considered for inclusion in the F-gas regulations.

### **Cosmetics**

Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (the GB Cosmetic Regulation) provides the framework for the regulation of cosmetic products placed on the GB market. Under the GB Cosmetic Regulation, the Secretary of State has powers to prohibit or restrict the use of substances where there is a potential risk to human health arising from the use of a substance in a cosmetic product and also to prohibit or restrict the use of carcinogenic, mutagenic and reprotoxic (CMR) substances classified under the GB CLP Regulation.

Since PFAS with known uses in cosmetics (such as perfluorodecalin) are not classified as hazardous to human health, no action would be taken to control their use under this legislation.

## **End of life vehicles**

The automotive sector is a major user of fluoropolymer components and F-gases in air conditioning. Regulations cover the depollution of vehicles at dismantling sites, with the aim of ensuring all vehicle materials and liquids are reused, recycled or safely disposed of. This includes the removal and collection of waste oils. Currently, there is no specific requirement to recover PFAS. Further investigation of this is needed.

## **Food contact materials**

Regulation (EC) No 1935/2004 Materials and Articles in Contact with Food (England/Wales/Scotland/Northern Ireland) Regulations 2012 (as amended) provides that any material or article that is placed onto the market must be safe in expected use. There are currently no specific measures in place for PFAS in food contact materials, however COT have reviewed the EFSA report which could be used to inform future direction on recommendations on PFAS in food contact materials.

## **Public water supply regulations**

The setting of statutory standards defining the maximum acceptable concentrations for PFAS in drinking water would enable the DWI to take enforcement action if a water company was not fulfilling its obligations associated with PFAS monitoring and treatment. At present companies are taking actions to monitor and risk assess concentrations of PFAS in drinking water based upon a guideline value set out by the DWI. PFAS inputs to sewerage networks that come under the control of trade effluent consents could be subject to more stringent control, but it is difficult to foresee how inputs from domestic premises could be effectively controlled hence demonstrating the need to control PFAS at source to protect public health.

### **6.2.3 Voluntary actions**

Voluntary initiatives could be introduced in collaboration with industry to raise awareness of PFAS, encourage migration to alternative products and practices, and increase collection, reuse and recycling of materials where this represents the best practicable environmental option. Companies could:

- Communicate measures to reduce emissions to the environment throughout the whole supply chain without regulatory controls.
- Participate in, and facilitate, engagement with interested parties, including stakeholders and regulators.

A programme similar to the Voluntary Emissions Control Action Programme (VECAP) (<http://www.vecap.info/>) could be adopted. The VECAP was developed and implemented by manufacturers and users of several brominated flame retardants. The VECAP demonstrated that the affected industry was willing to take responsibility

for the management of flame retardants at the production and product manufacturing stage in an auditable way. It provided support and guidelines to participating companies on how to control and reduce potential emissions of flame retardants to the environment. It committed companies to continuous improvement, with an annual review through a survey, and encouraged users to adopt the industry's Code of Good Practice and BAT.

If a similar voluntary initiative were put in place for PFAS, some reduction in point source emissions from industrial facilities would be expected. Baseline and post-implementation monitoring would be required to quantify emissions and any reductions achieved. The take-up of such a scheme by downstream users would also affect the overall level of emission reduction achievable.

It is important to note that VECAP had no impact on articles (including those that are imported) as it was not designed to address service life emissions.

The PVC industry has developed a voluntary commitment, VinylPlus ([Home - VinylPlus](#)) that aims to increase the sustainability of the industry. The programme has set and monitors performance against targets under five themes:

- Controlled-loop management (recycling)
- Reducing organo-chlorine emissions
- Sustainable use of additives
- Sustainable use of energy and raw materials
- Sustainability awareness

The Agency concluded that voluntary initiatives could play a role in reducing PFAS emissions. However, it is difficult to see how this approach could be as effective or consistent as a UK REACH restriction, since it would not address the whole life cycle and depends on take-up by numerous companies across multiple industry sectors.

#### 6.2.4 Conclusions on the most appropriate (combination of) risk management options

There are many potential routes for regulatory activity, however the majority are limited in scope and may not address all the concerns which have been highlighted in this RMOA. Key concerns identified regarding PFAS within the scope of this RMOA<sup>39</sup> are:

- Evidence gaps in GB profile of PFAS, as UK REACH registrations are not a good indication of PFAS use in GB due to tonnage-linked data requirements,

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<sup>39</sup> To note this section be read in the context of the approach described in Section 1 on grouping.

and the presence of PFAS in imported articles and polymers, for which no registration is required.

- Some uses of PFAS are wide and dispersive with direct human exposure to consumers from a wide range of products including those impregnated into furniture and other textiles. These applications, as well as industrial processes and FFF, also account for the main sources of PFAS into the environment.
- Monitoring suggests there is widespread human and wildlife exposure via surface waters and groundwater, indicating potential for exposure via drinking water. Extreme persistence of these chemicals and difficulty removing PFAS using water purification techniques mean that levels will likely increase over time without intervention. At present blending and treatment with Granular Activated Carbon are employed by water companies for sites at risk.
- PFAS (and their arrowheads) have extremely long degradation half-lives. The potential effects as a result of continuous exposure of the environment and humans over their entire lifetimes are not well understood and is not possible to test for.
- Hazard data for arrowhead substances is available and has generally been used to flag these substances for action. Information on other PFAS – including substances which can be precursors or degrade to these known hazard substances is scarce. Conclusions on hazards using the assumption that the arrowhead will drive the concern is therefore necessary, in the absence of data on the PFAS group itself.
- Alternatives are available but more detailed analysis on the hazard profile and performance is required to establish their feasibility.

There are clearly uncertainties about the hazardous properties of PFAS, and many data gaps. In reviewing the hazards of arrowhead substances, to which specific groups of PFAS can degrade or be precursors of, the Agency has established:

- There is robust evidence that PFAS are extremely persistent due to their underlying C-F chemistry.
- PFAS are extremely challenging to remove from the environment and are not readily excreted by animals.
- PFAS are mostly mobile and as such can travel widely in the environment, and they have been detected in many disperse human and environmental samples.
- Although there are no known causes of significant health risks to people, the long-term effects of exposure are not well understood and the data are scarce with regard to human health toxicity.
- That due to their pervasive nature there is a potential for some PFAS to cause serious and/or irreversible damage to the environment.

- The scale of PFAS detected in the environment and the increased risk to drinking water sources is of particular concern due to the uncertainty of lifetime exposure.

Based on initial considerations of likely effectiveness and efficiency of options discussed above in this Section – and considering the Precautionary Principle – the Agency concludes that it would be appropriate to consider initiating some or all of the following risk management measures with regard to certain uses of PFAS:

**1. Preparation of background dossiers to potentially support one or more UK REACH restrictions of PFAS, including:**

- **the use and disposal of FFF where non-PFAS alternatives are available,**
- **other wide dispersive uses such as the application of coatings or use of cleaning agents,**
- **the manufacture and placing on the market of consumer articles from which PFAS are likely to be released into air, water or soil, or directly transferred to humans. This includes textiles, upholstery, leather, apparel, rugs and carpets, paints, varnishes, waxes and polishes, cleaning products. Consideration may be given to other consumer articles if other gaps are identified in consultation with other legislative regimes such as food contact materials.**

The evidence base on PFAS is evolving rapidly, given the widespread interest in the harm these substances may be causing. As sufficiently robust, up to date evidence needs to be gathered to support these REACH restrictions, it is suggested that this work is phased. Further information gathering as necessary will aid scoping, prioritisation and refinement within the suggested actions above. However, due to the evidence and slightly more comprehensive information on FFF, it is recommended that this is prioritised first for action. In order to avoid regrettable substitution, a group approach rather than a single broad proposal should be used throughout all of this work.

Exemptions could also be considered for PFAS (as individual substances or groups) for which comprehensive reliable evidence of low hazard or safe use can be provided or consideration may be given to exemption on socioeconomic grounds and subject to the availability of alternatives.

The restriction(s) set out above need not apply to low hazard groups or low risk uses, for example; fluoroplastics or fluoroelastomers (low hazard groups), intermediates, uses in sealed/contained systems (including use as heat exchange fluids in heat pumps and refrigeration systems), (low risk uses). These could be highlighted as derogations to any restriction proposal.

## **2. UK REACH authorisation of PFAS used in processing aids in the manufacture and processing of fluorinated polymers**

Authorisation has been identified for processing aids due to its ability to limit these substances to this particular use; authorisation requires emissions to be kept as low as technically possible so it would reduce the amount of PFAS being emitted into waste streams.

For these PFAS to be authorised, they will first have to be placed onto the list of substances of very high concern in the UK and followed up with listing on Annex 14 of UK REACH (which is the list of substances subject to authorisation).

Industry have currently identified the lack of viable alternatives due to the required performance of these substances. Authorisation would allow controlled use whilst researching a viable alternative.

## **3. Further evaluation and investigation of substances that have been highlighted to be of concern**

- The arrowhead substance TFA has been identified as a concern for developmental toxicity, it is noted that some of the substances in the HFCs, HFEs and HFOs group (i.e. a commercially significant, high tonnage group in the UK) are F-gases that may transform to TFA. Further assessment (e.g. substance evaluation within UK REACH or informal evaluation) could be carried out on the arrowhead substance TFA and its precursors due to the concern highlighted for developmental toxicity. Such an exercise could be extended to other registered PFAS to assess whether additional data could be sought to clarify the risks they pose to the environment and human health. For formal evaluation of a substance under UK REACH the substance would have to be registered. TFA is not currently registered. For TFA, and also EEA-NH4 which also has concerns on reproductive toxicity, an MCL report could be considered to look into ensuring the substances have the correct classification and can be managed accordingly.
- Investigation and possibly Substance Evaluation under UK REACH could be carried out for some PFAS groups within the scope of this RMOA which do not degrade to arrowheads of concern, such as the perfluoroalkanes and perfluorocycloalkanes. These substances do have UK REACH registrations in place and are of concern with respect to their estimated emissions.

## **4. Continued collaborative work across government and with external stakeholders to bring together work on PFAS strategically**

The continued strategic consideration of PFAS to bring together strands of work would be a useful way of joining up the various concerns on PFAS, there are aspects such as decontamination, food contact materials and public



health which form part of an overarching picture. Some of these sectors have been touched upon above in this RMOA. The RMOA is part of a programme of work across government to inform further direction on PFAS.

This collaborative work could be strongly focused on progression of some of the possible regulatory changes mentioned within this document, but which are not within the legislative remit of the parties involved in drafting. These are:

**A review of the F-gas regulations to determine whether additional PFAS registered under UK REACH should be brought within scope**

- **Development of statutory standards for PFAS in drinking water in England and Wales**
- **This is likely to be considered by a future drinking water advisory board on standards.**

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